THE UNIVERSITY
of EDINBURGH

TWO SIDES OF THE SAME COIN: Patient Adherence and Staff Turnover in Substance Misuse Settings

By

Maeve Butler
Doctorate in Clinical Psychology (DClinPsychol)
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Factors Associated With Staff Turnover in Substance Misuse Services: A Systematic Review

Empirical Study:
A Grounded Theory of HCV Treatment Adherence in People who Inject Drugs

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Thesis		✓

Submitted in part fulfilment of the degree of doctorate in Clinical Psychology at the University of Edinburgh

Date Submitted: 01/05/2017

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Finally, in an era of surging divisiveness, this thesis is a dedication to the truth and power of human compassion and resilience.

With great suffering comes great compassion.

[a] Ryle, A. & Kerr, I.B. (2002). Introducing Cognitive Analytic Therapy: Principles and Practice. Chichester, UK: John Wiley.

Thesis Abstract

This thesis portfolio includes two studies, a qualitative grounded theory of treatment adherence in people who inject drugs (PWID) and a systematic review of staff turnover in substance misuse services. The empirical paper is presented first, the findings of which led to the systematic review. The qualitative interview study arose from observations made within a clinical trial for the treatment of chronic Hepatitis C (HCV). The Chief Investigator of the ERADICATE trial team initially approached the Adult Psychological Therapies Service to investigate what seemed to be an anomaly – patient engagement with HCV treatment had far exceeded expectations. Indeed, positive treatment adherence is not common among PWID. What is more remarkable is participants continued the trial while experiencing the highly aversive side-effects of interferon, a medication known to mimic opioid withdrawal.

It is important, if not crucial, to acknowledge the wider socio-cultural context in which this thesis portfolio was produced; the political landscape changed significantly over the course of writing. Divisive judgements about what characteristics make a person worthy and deserving of resources, became more dominant in public discourse and heightened the author's awareness to these aspects in the data. PWID are among the most marginalised, and stigmatised groups in society. Several of the participants interviewed were homeless and all were at various points on a relapsing trajectory of injecting drug use. Perhaps positive treatment adherence in this population is counter-intuitive because intuition is often based on assumptions derived from implicit biases. Indeed, until 2008, Scottish policy systematically denied HCV treatment to PWID. Due to the assumption that re-infection was inevitable, treatment was seen to be wasteful. Epidemiological studies now show is that public health is significantly improved when PWID are treated, as population prevalence goes down.

Completing this thesis led to an examination of fundamental assumptions, not just relating to the participants or the data, but also relating to the question of what Clinical Psychology is. What can we contribute to the science of human behaviour? How does a self-aware mind arise and become autonomous? What leads adults to mentalize and enact their intentionality through particular behaviours, like taking medication? In grappling with these questions, the reader will detect the influence of developmental theorists, Vygotsky, Erikson and Bowlby. Seminal experiments, such as Tronick's still face (Tronick, 1989)[1] and Harlow's monkeys (Harlow and Zimmerman, 1958)[2], alongside newer fields of interpersonal neurobiology and developmental trauma have supplied the soil in which to ground the data gathered in this

[1] Tronick, E.Z. (1989). Emotions and emotional communication in infants. *The American Psychologist,* 44, 112–119.

[2] Harlow, H. F., & Zimmermann, R. R. (1958). The development of affective responsiveness in infant monkeys. *Proceedings of the American Philosophical Society*, 102, 501 -509.

study. From our earliest days we are designed to absorb stimuli and integrate our perception into a gestalt. When PWID are characterised as "chaotic", there is a failure to appreciate what this may really reflect: difficulty making sense of internal experience resulting in the absence of order, coherence and meaning. Therefore, the ontological presupposition underlying both the empirical paper and systematic review, is that humans are resilient, relational beings. When the correct conditions and contingencies are in place, our innate propensity to learn and grow can manifest in positive, adaptive behaviour.

Narratives are not only ways of seeing the world, but ways of constructing it; we live through and are created by the stories told by others and ourselves (Murray, 2003)[3]. The public narrative of scepticism that has emerged around scientific endeavour, makes it all the more incumbent upon researchers to carry out their work with personal conviction, integrity and transparency (Rea, 2017, February 22)[4]. This qualitative analysis was completed with a high level of scientific rigour. Indicators of quality were employed throughout, for example, particular attention was paid to preserving the colloquial expression of participants in transcription and substantiates the authentic representation of their voice.

The resultant grounded theory shows that the interpersonal context is a key part of adherence behaviour among PWID. This finding precipitated another question, if good quality relationships are important for patient engagement, how do staff stay engaged in the task of providing consistent, sensitive care on a sustained basis? The current evidence base on supporting and preserving compassion did not substantiate a systematic review, however, the opposite phenomenon, people leaving their jobs has been explored. As Clinical Psychologists we are able to connect with and influence different audiences by skilfully adapting our language. In order to appeal to managers and team leaders, the most pragmatic way of framing staff disengagement, was to examine actual staff turnover as a 'hard', concrete outcome. The methodological quality of studies included for review was reasonable in the context of methodological limitations. Findings point to the importance of collective support, good quality relationships and job satisfaction in mitigating against turnover in substance misuse services.

This thesis portfolio is a sensitive and pragmatic understanding of engagement in both PWID and staff with the respective systems within which they are embedded. The results are contextualised and oriented toward medical colleagues working in HCV treatment, service leaders and fellow applied psychologists.

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[3] Murray, M. (2003). Narrative psychology. Qualitative psychology: A practical guide to research methods, 111-131.

[4] Rea, S. (2017, February 22). Uncertainty perception drives public's trust, mistrust of science [webpage]. Retrieved from https://phys.org/news/2017-02-uncertainty-perception-mistrust-science.html

Chapter 1:

A Grounded Theory of HCV Treatment Adherence in People who Inject Drugs

Carolyn Maeve Butler[ab,5], David Gillanders[a] , Kevin Power[b], and Kirsty Gillings[c]

[a] School of Health and Social Sciences, The University of Edinburgh, Teviot Place, Edinburgh, Scotland, UK, EH8 9AG.

[b] NHS Tayside Psychological Therapies Service, Dundee Health and Social Care Partnership,15 Dudhope Terrace, Dundee, Scotland, UK, DD3 6HH.

[c] NHS Fife, Psychology Department, Stratheden Hospital, Cupar, Fife, Scotland, UK, KY15 5RR.

(for submission to Harm Reduction Journal see Appendix VIII)

[5] Corresponding postal address: NHS Tayside Psychological Therapies Service, Dundee Health and Social Care Partnership, 15 Dudhope Terrace, Dundee, Scotland, UK, DD3 6HH. Tel: 01382 346 556; *E-mail address:* maeve.butler@nhs.net

Abstract:

Background: Chronic Hepatitis C (HCV) is a significant public health threat largely affecting people who inject drugs (PWID). Positive antiretroviral treatment adherence is an uncommon and poorly understood phenomenon in this population. This study seeks to conceptualise this behaviour in a sub-sample of PWID who participated in a drug treatment trial for HCV.

Method: Semi-structured interviews were conducted with fifteen participants who had demonstrated positive adherence within the ERADICATE HCV drug treatment trial. Participants had successfully attended weekly clinic appointments and complied with a self-administered medication regime for a recommended duration. Participants engaged for an average of 21 weeks and were interviewed during the 3, 6 or 12 month follow-up period.

Results: Analysis followed social constructivist grounded theory approach of open and focussed coding, categorising and theoretical comparison. Analysis was a reflective, reflexive process supported by the lead author's journal writing, use of supervision and member-checking. The result is a pragmatic model of treatment adherence from a psychological perspective, charting the influence of intrapsychic, socio-cultural and interpersonal contexts on engagement and adherence. The theory outlines three key themes. These reflect the processes of moving away from states of mistrust, shame and guilt and moving toward trust, autonomy and connection. Adherence was captured as the culmination of hope, agency and purpose as emergent qualities. Analysis of the data was also informed by developmental perspective, conceptualising adherence as a dynamic, shifting process rather than a static outcome, as evidenced by the data.

Conclusion: Findings should be considered by professionals working in substance misuse and those providing HCV treatment. The resulting theory supports a holistic understanding of the facilitators of treatment engagement and positive adherence. Logistical and structural aspects of service provision should maximise flexibility and access. Frontline workers should be supported by managers to provide consistent, sensitive, compassionate care through training and capacity planning.

Keywords: HCV, hepatitis C, treatment, adherence, engagement, injecting, heroin, qualitative, interview, grounded theory.

8,553 words

Introduction

Background

As a primary cause of liver related morbidity and mortality, chronic hepatitis C (HCV) is a global public health threat (Leask & Dillon, 2016). Over 185 million people are currently infected worldwide and the prevalence of liver cirrhosis in untreated patients is set to increase (Davis, Alter, Serag, Poynard, & Jennings, 2010; Hanafiah et al., 2013). In the UK, the demand for HCV related liver transplants is rising (Public Health England, 2014). Estimates predict that at current treatment rates, chronic HCV will lead to the death of one million people in the United States by 2060 (Rein et al., 2011). Moreover, HCV is now the most common cause of death in HIV-positive patients on highly active antiretroviral therapy (ART) (The Antiretroviral Therapy Cohort Collaboration, 2010).

The disease burden for HCV falls disproportionately on marginalised social groups (Rich et al., 2016). HCV prevalence is highest among people who inject drugs (PWID), with infected equipment representing a major route of transmission (Nelson et al., 2012). Before the enactment of the Hepatitis C Action Plan for Scotland II (The Scottish Government, 2008) intravenous drug use (IDU) was considered a contraindication for ART (see Health Protection Scotland, 2007). Treatment was withheld from this population based on the assumption that chaotic lifestyles lead to re-infection, thereby negating the outcome of successful treatment. This supposition has not been supported by empirical evidence; PWID have been shown to achieve as good, or better HCV treatment outcomes compared to other groups (Bojovic et al., 2013). Epidemiological modelling studies have shown that the policy of 'treatment as prevention' has the potential to eradicate the HCV virus as population prevalence decreases when PWID are treated (Leask & Dillon, 2016).

In the past decade, international and national clinical practice guidelines have adopted the position that there should be equity of access to HCV treatment for all patients. While the National Institute for Clinical Excellence (NICE, 2004) and European Association for the Study of Liver (Back, 2016) advocate that IDU is no longer a contraindication to HCV treatment, access remains poor and inclusion arbitrary (Martin et al., 2011). Within Europe, prevention strategies and coverage of HCV interventions continues to be highly variable (Aspinall et al., 2016). A UK audit showed that 10 out of 69 hospitals refused HCV treatment to all PWID (All-Party Parliamentary Hepatology Group, 2010). Further concerns have been raised regarding discriminatory attitudes and other factors which may impede the delivery of HCV treatment in drug and alcohol services (Treloar & Fraser, 2009). HCV has been described as a "changing epidemic" (Wandeler, et al., 2015), referring to the advent of direct-acting antiviral drugs that are more tolerable and faster acting than previous interferon based combinations (Barth, 2015).

These new preparations are expensive however, and "high HCV treatment costs have stimulated an ethical debate on whom to treat and whom not to" (p. 730, Barth, 2015). The moral dilemma of resource allocation is compounded by a lack of guidance around the use of behavioural interventions to optimise adherence. This is a pertinent issue; despite technological advances, the adage that 'drugs can't work if people don't take them' remains true (Ho, Bryson, & Rumsfeld, 2009). Sub-optimal adherence precipitates numerous adverse outcomes, including drug resistance (Afdhal, Zeuzem, Kwo, Chojkier, Gitlin et al., 2014). Therefore, understanding adherence is crucial to maximising the success of efforts to contain and potentially eradicate the HCV virus.

Adherence

A standard clinical definition of adherence does not exist, though attempts have been made to unify the lexicon of terms used to describe medication use, including "compliance", "concordance" and "persistence" (Cramer et al., 2008). Adherence has been operationalised as: the extent of patient conformity to recommendations given by the healthcare provider on "the timing, dosage, and frequency" of medication intake over a prescribed duration (p.46, Cramer et al., 2008). The qualitative evidence base on HCV treatment adherence has adopted a broader understanding of the construct by including barriers and facilitators of adherence behaviour (e.g. Sublette, Smith, George, McCaffery, & Douglas, 2015). Evon and colleagues (Evon, Donna, Golin, Bonner, Jason, Grodensky et al., 2015) related their findings from an interview study, to the Information-Motivation-Behaviour Skills (IMB) Model of Adherence (Fisher, Fisher, Amico, & Harman, 2006), which has been commonly used to conceptualise ART adherence in HIV. The IMB model posits that patients who are well informed about treatment, have internal and external motivation, and possess effective behavioural skills, will be more likely to adhere to treatment. The model has been critiqued for a focus on the rational synthesis of information, which has been shown to be an inconsistent predictor of behaviour and a lack of attention to the role of environmental and cultural factors in adherence (Sharma, 2012).

Other studies have also drawn conclusions about the nature of adherence among PWID, with varying degrees of rigour. A meta-synthesis of qualitative studies examining HCV treatment adherence among PWID (Rich et al., 2016) reported a number of observations: (a). studies were heavily concentrated on populations in Australia and the USA; only one out of the ten studies reviewed was completed with UK based participants; (b). most studies did not describe their epistemological position, nor the interpretive stance of the researcher. Most referred loosely to a coding process that employed thematic analysis. Just one study referred to a "constructivist orientation" in their analysis (see Rasi et al., 2014); (c). two themes were identified as the most prominent facilitators of HCV treatment adherence, including logistical

health system factors, such as integrated services, and positive support from staff and peers. A third theme captured the role of the drug user identity as a source of struggle during treatment. (d). the Critical Appraisal Skills Programme (CASP) was used to appraise the quality of the research. Such structured approaches to evaluating qualitative studies have been found to be useful for judging procedural aspects of research in terms of methodological practice, but have been critiqued for being "less insightful and [making] weaker contributions towards the conceptual development" of an area (p.45., Dixon-woods et al., 2007). The lack of theoretical linkage between themes described by Rich et al. (2016) can lead to conceptualisations appearing disconnected and piecemeal. This is a limitation in the current qualitative research evidence base on HCV treatment adherence.

Current Study

Our understanding of adherence in HCV treatment has been developed principally from the perspective of public health medicine and sociology (e.g. Harris, Rhodes, & Martin, 2013; Treloar, Rance, Grebely, & Dore, 2013). In the latest publication from the European Monitoring Centre for Drugs and Drug Addiction, Harris and Rhodes, (2016) describe "enabling environments" as a framework for understanding engagement, initiation and access to HCV treatment. This integrative approach presents a rich outline of contextual forces that facilitate uptake of treatment. There is an opportunity to develop a unified understanding of positive HCV treatment adherence from a psychological vantage point, combining systemic and individual aspects. Researchers have called on Clinical Psychologists to apply their skills in formulating complex treatment issues to socially excluded groups (Maguire, 2015). The voices of PWID based in the UK are currently under-represented in the literature and extrapolating findings from different socio-cultural contexts is problematic. For example, the socioeconomic demographic, service provision model, and healthcare funding relevant to an Australian population differs from the UK (e.g. Sublette et al., 2015).

To summarise, lack of rigour in the existing qualitative evidence base has resulted in a fragmentary understanding of treatment adherence, which lacks theoretical clarity. Therefore existing knowledge is more difficult to apply clinically, reducing the actual benefit to the patient. The current study adopted a robust epistemological position that supported pragmatism and integration in the field of qualitative HCV treatment research. This aim was achieved by focussing on positive adherence behaviour in a novel socioeconomic and treatment context, among cohort of PWID receiving HCV treatment in Scotland. The shortcomings of previous studies were addressed using rigorous methods of sampling, data gathering and analysis.

Method

Design

A qualitative methodology was employed for this study, using individual semi-structured interviews that were recorded and transcribed, then subject to grounded theory analysis.

Treatment Context

This study recruited participants engaged in the ERADICATE Hepatitis C drug treatment trial (International Standard Randomised Controlled Trials Registration: http://www.isrctn.com/ISRCTN27564683). The trial has been recruiting since 2013 and provided treatment using combination, pegylated interferon and ribavirin based therapy, to people actively injecting drugs. The overall "cure rate" (undetectable viral load at 3 month follow-up) for the whole cohort, in March 2017 was 84.5%. This is significantly higher than a pooled cure rate of 55.5% reported in a meta-analysis of 36 HCV treatment studies (Dimova et al., 2013). The trial is ongoing and is based at an urban Needle Exchange Clinic, co-located at a community centre offering intensive support programmes to the local substance misuse population in partnership with Local Authorities and NHS health boards. The trial regime required home-based self-administration of antiviral medications on a daily basis, and attendance at weekly clinic appointments with one of two trial nurses, to receive an injection. The study used the following incentives: for each appointment attended, participants received a weekly supply of protein drinks and a £10 voucher for a large chain supermarket. At each appointment, participants underwent urine drug screening, viral blood count, pill counts and assessment of treatment side effects.

Sampling

To be considered for inclusion in this study, potential participants had to have demonstrated positive adherence by engaging in the treatment for the period recommended to achieve SVR (sustained virologic response, also referred to as "clearance") within the ERADICATE trial (24 weeks for HCV Genotype 1 and 16 weeks for HCV Genotype 3)[6].Nurses monitored medication adherence on a weekly basis by using pill counts and recording attendance at appointments. Positive adherence behaviour was demonstrated by 91.9% of the whole cohort, at the time of data collection (commenced in February 2016). This contrasts to discontinuation rates of up to 27% for similar clinical trials (Mulhall & Younossi, 2005). In consultation with the ERADICATE research team, the phenomenon of positive adherence was deemed to warrant specific investigation. Therefore, non-completers were not included, as they

[6] See Appendix I p.47 for full inclusion and exclusion criteria for the trial.

represented a significant minority of the cohort and had not been contactable by staff after disengaging from the trial.

In total, seventeen participants were approached to engage in the study; two agreed to participate but did not attend, and did not respond to subsequent attempts at contact from staff. Therefore, in-depth semi-structured interviews were conducted with fifteen trial participants, representing 88% of those approached, and 14% of the total trial cohort who had engaged (N=106) Following the initial identification of participants via purposive sampling (criterion-driven as indicated by the parameters of inclusion), theoretical sampling (data driven) was also employed. As several participants had spoken about their families, children and peers being relevant to their engagement in treatment, the partner of one participant who had also completed HCV treatment within the trial was recruited. This decision was based on data from three participants linking adherence behaviour to support from their partner.

Data Collection

Data were collected between February and April 2016, by the lead author. The two trial nurses and harm reduction staff within the Needle Exchange Clinic initially approached eligible trial participants, and provided them with an information sheet and a verbal description of the interview study. Those interested were invited by the clinic staff member to meet the Researcher on a one-to-one basis. Participants were assured that their anonymity would be protected, and that their responses would not have any influence on their relationship with any staff members, or subsequent treatment. If participants were agreeable, they provided their written consent to participate. Participants were given a £10 supermarket voucher for participating. Interviews lasted an average of 36.23 minutes (range = 21.43 - 46.33 mins.).

A topic guide was used to support the interview conversation without compromising a neutral, exploratory approach to the unfolding of data (see Appendix I, p62.). Open questions were used to initiate dialogue e.g. “Tell me about your experience of the ERADICATE trial”. These were followed with prompts and probes to explore the content that participants offered. As data was collected and reviewed concurrently, associated and emergent issues were incorporated into subsequent interviews as per the grounded theory method (Charmaz, 2006).

Analysis

A social constructionist grounded theory approach was adopted as the epistemological stance to data analysis (Charmaz, 2006; Strauss & Corbin, 1990). Grounded theory seeks to explain how social structures and processes lead to the emergence of phenomena through interactive contexts (Starks & Trinidad, 2007), and explicitly examines the relationships among

these elements (Strauss & Corbin, 1990). The approach is suited to conceptualising change processes (Morse & Johnson, 1991).

Over nine hours of interview data were digitally recorded, transcribed verbatim, systematically coded and analysed. A minimum of two reviews of each script was undertaken. Textual data was coded in NVivo 11.0 software using the constant comparative method (Glaser, 1978; Strauss & Corbin, 1990). Data was continually checked against previous data and relevant literature. A series of three steps informed the analytic process: (a) open, line-by-line coding, using all participants' language without imposing preconceived interpretations (see Appendix III); 1,143 codes were generated at this stage. As the analysis proceeded, memo writing supported focused and higher order coding; (b) axial coding - clustering data to form abstract concepts and categories (see Appendix IV); and (c) theorising - generating an integrative explanatory framework by linking categories. A significant period of time was spent in immersion with the data and context, including clinic observations, discussion and liaison with members of the research team and extensive reflection on the process through the lead author's journal writing. Each stage of the analysis was supported by monthly supervision, which included comparing codes and reviewing the development from line by line codes, to sub-categories, categories and overarching themes. The depth of discussion is demonstrated in post-supervision journal entries (see Appendix IV).

In line with principles of good quality qualitative research (see Cohen & Crabtree, 2008), this study employed methods suggested by Mays & Pope (2000) to support the trustworthiness and credibility of the results:

(i). Fair dealing: An iterative approach to data collection and analysis was employed. Data collection was continued until analysis indicated that theoretical sufficiency had been reached based on decreasing frequency of new axial codes and increasing abstraction. Alternative conceptualisations were considered for negative cases, which did not appear to fit with existing data. The construction of a theory is akin to producing a relational frame. Language acts as a bridge between the inner world of the participant and their external context. Therefore, quotes are presented in the actual vernacular of participants to enhance the authenticity of the themes being grounded in the data. Meanings and translations are provided where necessary to support clarity and coherence within the narrative.

(ii). Triangulation: Data from multiple interviews was compared both within and across transcripts and codes to ensure comprehensiveness. The resultant grounded theory was member checked by the two ERADICATE trial nurses.

(iii). Reflexivity: Reflective memos documenting the researcher's process acted as an audit trail for decisions made regarding the analysis and to ensure no data was lost due to flawed recall or inaudibility of recordings. A selection of codes was randomly spot checked by a member of the research team. Differences in coding were discussed by returning to relevant extracts of raw data. A synthesised version of the analysis is presented; the full text is available via correspondence with the lead author.

Results

Participants

All participants had demonstrated positive adherence by successfully completing the minimum period recommended for HCV treatment effectiveness within the ERADICATE trial (24 weeks for HCV Genotype 1 and 16 weeks for HCV Genotype 3). Four participants concluded treatment before the full duration of 24 or 16 weeks. In each case this was done under the guidance of the trial nurses, due to early SVR. Almost all participants had achieved SVR (N=14, 93%). The one participant that did not achieve clearance had engaged fully for the recommended period (16/16 weeks). One participant completed an extra 12 weeks of treatment (24/16 weeks), an additional option offered within the trial, undertaken at the discretion of the participant. At the time of starting the ERADICATE trial, all were actively injecting drugs, no participant demonstrated liver fibrosis or high levels of cirrhosis and no participant had received HCV treatment previously. Participants were interviewed within the period of their three or six month follow-up. All participants identified as British Caucasian. The average age of the sample was 36 years old (ranging from 28-46). Two-thirds of the sample were male, which was approximately the same ratio as that of the larger cohort. The majority of participants were interviewed within the 3 or 6 month follow-up period after concluding the 16 or 24 week treatment (N=13, 87%). Eight participants reported a forensic history and none were in paid employment. Other characteristics of the sample are outlined in Table 1.

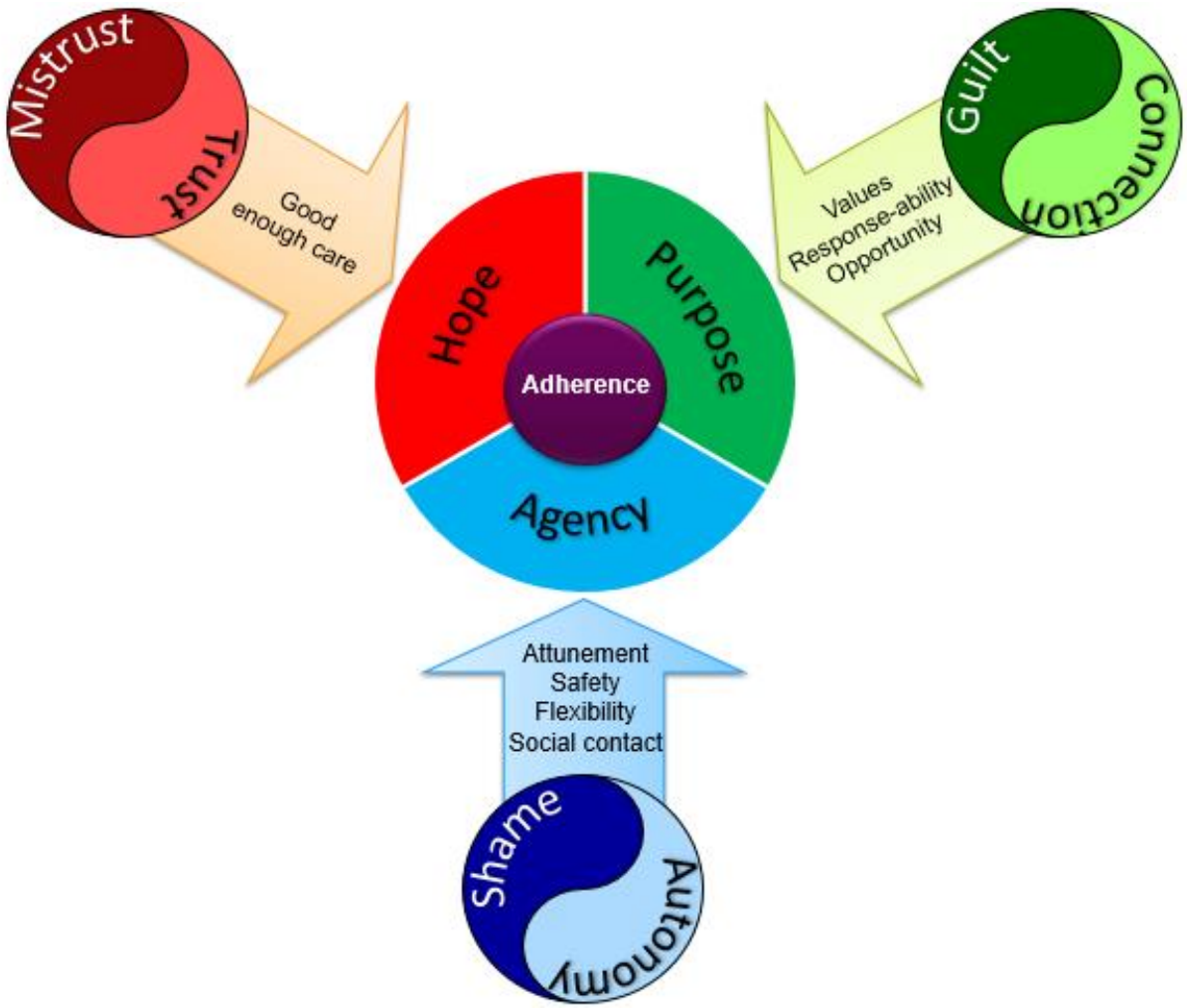
Grounded Theory

This grounded theory outlines a trajectory of behaviour change, in which participants shifted between contrasting positions. The data that emerged moved from an exclusive focus on HCV treatment adherence to incorporate the meaning of the HCV virus to participants. The resulting grounded theory conceptualises HCV treatment adherence within the framework of three overarching core themes: hope, agency and purpose. These reflect the qualities that emerged from the reconciliation and resolution of opposing forces (sub-categories). The specific conditions and contingencies which enabled participants to move between these stages is outlined.

Participant No. [by order of interview]	Participant pseudonym[7]	Length of Interview (min.sec.)	Demographics			Health			
			Age	*Gender*	*Accommodation Status*	*Achieved SVR (HCV "clearance")*	*No. weeks engaged / no. weeks. recommended*	*Genotype of HCV Virus*	*Stage of Treatment Follow-up at Interview*
1.	"Laura"	41.36	30	F	Independent	Y	13/16*	3	3 month
2.	"David"	46.33	43	M	Independent	Y	24/24	1	3 month
3.	"Matt"	38.24	46	M	Independent	Y	24/24	1	3 month
4.	"Jack"	33.30	40	M	Homeless-street	Y	21/24*	1	6 month
5.	"Dean"	40.22	34	M	Hostel	Y	24/24	1	3 month
6.	"Rick"	46.51	33	M	Independent	Y	24/24	1	3 month
7.	"Sean"	45.55	44	M	Independent	Y	24/24	1	6 month
8.	"Peter"	43.11	41	M	Independent	Y	8/16*	3	3 month
9.	"Will"	21.43	31	M	Hostel	Y	24/16	3	12 month
10.	"Mike"^	40.10	38	M	Family	Y	24/24	1	6 month
11.	"Zara"^	22.09	36	F	Family	Y	24/24	1	12 month
12.	"Gemma"	37.50	33	F	Independent	Y	24/16	3	6 month
13.	"Lisa"	40.41	30	F	Independent	Y	24/24	1	3 month
14.	"Walter"	21.50	28	M	Independent	Y	18/24*	1	6 month
15.	"Sarah"	25.04	35	F	Hostel	N	16/16	3	3 month

Table 1. Sample Characteristics *Early responders ^Two participants linked as partners

[7] Participants are referred to by a fictitious name throughout.



Model 1: HCV Treatment Adherence: Core Themes, Categories and Sub-categories

Theme I: Letting Go and Letting In

The first main theme outlines the process of letting go of mistrustful perceptions, and allowing faith and hope to be placed in the trial nurses and the treatment.

Mistrust:

The social world of PWID is characterised by mistrust, with persistent risks of harm, victimisation, and exploitation. There is a latent expectation that others behave disingenuously and inconsistently which leads to defensiveness and detachment:

> *"I don' really associate wi' people abou' here, they're all two faced"* (Zara)

The majority of participants spoke of isolation; the view that *"I've got no one"* (Peter) was common and entrenched. Furthermore, the peer context constructed treatment as a harrowing, distressing process, creating a subjective norm that treatment was *"brutal"* (Walter). When asked "How confident were you in the treatment?". Mike responded:

> *"Oh I wasn't no ... I'd heard a lot 'a y'know in drug circles ... all these different horror stories 'oh that treatment was hell it was the side-effects was really bad an' it didn' work an' I only lasted three weeks'"* (Mike)

"Good enough" care:

The theme of mistrust contrasted sharply with participants' perception of the trial nurses and how they felt they could trust them:

> *"They're no people tha' are gonna lie to yer face so 'ken it kinda makes it like ... you trust them"* (Dean)

Confidence in nurses' ingenuity and positive intention was key to unlocking participants' openness and willingness to engage in treatment. Speaking about his lack of understanding of the virus and treatment, Dean states, *"I dinnae ha' (did not have) a clue wha' they were on abou'.* The capacity to let go of the *"horror stories"* surrounding treatment and consider the possibility of clearing the virus, was related to a felt sense of the nurses' integrity and transparency.

> *"I 'ken'd (knew) tha' wha'ever they done to us 'ken (you know) it was for a good reason"* (Dean)

Nurses' portrayed a number of personal qualities and behaviours that provided the stimulus for participants to engage with them. Salient features of this interpersonal context were safety, consistency and sensitivity. Interactions were imbued with kindness and unconditional positive regard, precipitating trust. Time to talk was a key for participants to share their life experiences

and disclose personal experiences. Non-judgemental responses were particularly important as most participants were engaged in ongoing IDU:

> *"They would never ever look down at ya if say for instance you were going through your Hep treatment and you used heroin they would never be like that's a waste yer treatment"* (Laura)

Receiving interpersonal warmth and being listened to, had a powerful, humanising impact in worlds deprived of connection:

> *"They [the nurses] jus' make you feel like a nor- like a human bein' and when I was at the stage when I didn't feel like a human bein' I didn't feel like part of the society an' things ay"* (Sean)

Nurses were available on a consistent basis, in person and remotely by mobile phone, under the proviso of an open invitation for contact. Participants were confident in receiving a prompt response and believed that *"they're helpful an' they're there if you need them"* (Sally). The experience of sensitive responsivity led participants to develop an expectation of care that was reliable and safe.

HCV was perceived to be more treatable than other blood borne viruses, as "*it's not like HIV*" (Sally). Further exploration of confidence in initiating treatment however, revealed ambivalence and low expectation among some participants:

> *"I jus' had to wait an' see … I mean it could work an' it migh' no work"* (Sally)
> *"I probably looked on the negative side … so I wasn' settin' mysel' up for a fall if it didn' work"* (Sean)

Others stated that just knowing *"there was a treatment available an' it gave me a chance of gettin' rid of it"* (Rob) was enough to undertake treatment. This variability indicates that the willingness to undertake treatment was not fully accounted for by intellectual perceptions of treatability, but also by the felt sense of hope instilled by the care provided. Concrete knowledge was secondary to the faith derived from the relationship with staff:

> *"[the nurses] like tellin' us about it they never says it was a hundred percent bu' I put my trust into them … I trusted that it worked"* (Lisa)

Theme II: Showing up and Enacting Agency

The second main theme outlines the process of mentally and physically 'showing up' for treatment. This required the reconciliation of painful feelings, particularly shame and stigma, to enact personal agency and autonomy in the form of adherence behaviour.

Shame:

The diagnosis provoked a feeling of being less than, worthless and powerless; for Peter it was *"like I was a sec- second class citizen because I had Hepatitis C"* (Peter). Similarly, when Jack was

diagnosed, he felt *"absolutely gutted felt disgusted wi' myself felt dirty jus' ashamed 'a mysel'"* (Jack). Language used by participants to refer to the HCV virus conjured images of 'dirt', decay, and degradation, synonymous with IDU. Rob stated that HCV is *"a junkie's disease"* (Rob). Positive status was linked with the stereotype of PWID as irresponsible, chaotic and careless:

> *"Jus' comes wi' a kinda stigma does it 'ken Hep C ay dirty junkie sits an' shares needles all the time sit in basement flats or drug dens an' jus' pass the needles aroun'"* (Jack)

The virus was understood as an 'other' that invaded and sullied the self-concept. Participants expressed the drive to "get rid of" this part as a means of countering shame.

Stigma and un-deserving:

PWID experience stigma within micro and macro level social contexts. Rob plays "devil's advocate" by espousing popular attitudes to funding HCV treatment for PWID; this evocation is underlined by internalised, or self-stigma:

> *"Why should we pay to cure drug addicts 'a Hepatitis jus' for 'em to continue usin' drugs anyway*" (Rob)

Fear of stigma from others prevented some participants from disclosing their status. This burden to live in secrecy, perpetuated shame by provoking feelings of incongruence:

> *"None of my friends knew that I had it am... I jus' couldn' tell them that I had it cos' I was ashamed of myself that I caught it"* (Laura)

Due to misperceptions around the communicability of the virus, Laura's family imposed restrictions on her to minimise the perceived risk of transmission, leading to physical and emotional segregation:

> *"It didn' just feel right like not being able to put my cup beside my family' cups and cutlery I put [them] in the cupboard wasn' allowed to put it in the drawer"* (Laura)

For PWID, stigma appears to extend beyond the kitchen table, it is wound and bound into our socio-political fabric. PWID are embedded in political structures and internal procedures that uphold contingencies of deservedness. The data describes that PWID are subject to pervasive societal narratives about their 'worth'. Matt's account speaks to ideals of equality in treatment access, as demonstrated by the inclusion of those currently injecting drugs in the trial:

> *"It shows the government tha' y'know people still everybody matters y'know wha' I mean it's not just people that's maybe in recovery"* (Matt)

The physical and emotional struggle:

Side effects were a challenging aspect of HCV treatment and frequently initiated a conflict between the desire for a cure and physical suffering:

> *"It was on occasion I felt like jus' sayin' nah I I I cannae do this this is too painful … bugger this I need'a stop cos I cannae do it"* (Mike)

Skin irritation, extreme fatigue, hair thinning, cold/flu symptoms were included in a long list of symptoms experienced. The fortified protein drinks provided as an incentive for attending appointments were typically used for meal replacement where gastro-intestinal issues caused significant appetite and weight loss. Side-effects precipitated a lack of normality and unpredictability, which could be frightening and made life "*mair chaotic*" (Mike). Physical withdrawal and disengagement were strategies used to manage pain, low mood and suicidality, exacerbating feelings of disconnection and isolation. Nurses offered a compassionate, validating response by normalising side-effects:

> *"I was noticing like hair falling out an' they would they would make you feel like didn' worry about it it's ok it happens to everybody it's not just you"* (Gemma)

Personalised education and empowerment:

Explicit explanations of the treatment procedure, phlebotomy skills and timely individualised feedback on viral load were valued by participants. Walter appreciated how *"they [the nurses] was on top a' things keepin' me informed"* (Walter). The provision of education was important for challenging stigma, for example, Laura brought her mother to clinic and nurses corrected misinformation about the risk of transmission. Information could also have the opposite effect; some participants said they *"purposely didn' want to know abou' side-effects"* (Walter) as they anticipated that this would negatively influence their experience of the medication:

> *"A lotta people'll read up about it .. an' then all of a sudden they've got some 'a them (side-effects) … so I didn't want none 'a tha'"* (Matt)

Safety and discretion:

The centre has a widely respected reputation for providing specialised professional support to PWID. While Lisa felt she could relate to *"people obviously goin' through the same as what I was"* (Lisa), other participants, attempting to abstain from IDU valued discretion and anonymity:

> *"If yer tryin' to stay eway fre' drugs it's no easy go into tha' place [other substance misuse service] an' there's people sittin' takin' drugs … whereas when you come in here there's not"* (Sally)

> *"Naebody'd even 'ken wha' I'd even been here for 'ken so … it seemed easier tha' way"* (Dean)

The clinic was located in a separate part of the building with a concealed entrance. This maximised privacy, minimising the risk of exposure and accompanying sense of vulnerability. The importance of this ergonomic aspect was reinforced by participants commenting on their aversion to hospital environments. The large size and complexity of the hospital building was

not only more anxiety provoking by design, but was also associated with distressing memories of being judged for IUD. Gemma predicts that she would have disengaged from hospital based treatment, due to feeling shame, a contrast to how she felt at the centre:

> *"If I had to start tha' at the hospital I don't think I woulda went all the way through … I wouldn' went back" "at the hospital I would feel embarrassed an' ashamed an' stuff but here I didn'" (*Gemma)

Holistic needs-led support:

When support needs were systemic and pragmatic, nurses helped participants to resolve basic welfare issues by ordering food parcels and liaising with criminal justice services to facilitate treatment access. The trial clinic was co-located with harm reduction services, therefore many participants were already acquainted with the setting and the staff. The treatment was run with a collective team approach. Liaison and information sharing facilitated unified and continuous care. The staff within the centre acted as a 'home base', a source of containment of emotional states:

> *"If you were havin' like a bad day you know that if you were comin' in … you could talk to them"* (Lisa)

Flexibility and access:

A short wait to treat and drop-in appointment systems, comprising open slots and no 'did not attend' policy, supported attendance at appointments. This meant participants had a greater sense of ownership, and control over their engagement. Will captures the sentiment of many in stating, *"it was a lot easier bein' a drop-in"* (Will). There is a balance however between specificity and openness, restriction and freedom. While the flexibility of the drop-in system was important, the expectation that the clinic *"always"* being *"every Thursday"* (Jack) supported a sense of stability and predictability. The city centre location and accessibility by public transport were practically helpful, though two participants actively choose to come to the centre, rather than the hospital, attributing this to familiarity and trust, rather than convenience:

> *"I know the clinic I know the staff here … I mean like [the local hospital] is like 5 minutes from ma house [laughs]"* (Zara)

Structured social contact and esteem:

For participants who were otherwise disengaged from any kind of structured activity, attending treatment appointments provided an opportunity for social contact which improved mood. Mike conceptualises his own and his partner, Zara's attendance at the centre as an opportunity to socialise, and links this to feeling better:

> *"She [Zara] says "nah I like to get oot an' come doon an see them" an' then tha' was like maself … it kinda lifted ma spirits"* (Mike).

Multiple health and welfare services were available at the centre including a dental service, and a "recovery cafe". Gemma speaks of the interpersonal support she received from a group she attended at the centre during treatment:

> *"It was people to speak to an' never judged ya' they sorta understood listened to ya' … that did help me that group I needed that"* (Gemma)

Within the PWID community itself, treatment was held in a kind of mysterious esteem which roused the interest and curiosity of others. Those few participants who disclosed that they received treatment were awarded with kudos and status by their peers. They were viewed as experts-by-experience, and stepped into this authority to advise others:

> *"A lot 'a them asked wha' happened an' how does it work … an' I had to explain"* (Peter)

Theme III: Moving with Purpose

The third main theme outlines the process of channelling feelings of guilt and obligation into personal purpose, by embracing treatment as means of moving toward values and connection.

Guilt and obligation:

Some participants expressed a remorseful stance in relation to acquiring the virus. Guilt, as distinct from shame and self-stigma, had a more explicit other-orientated dimension. It arises from a moral transgression, a violation of a basic expectation that results in harm to another. Fear of transmission was a particularly striking source of self-blame in the narrative of participants who were parents:

> *"If my son caught that I wouldn' be able to live wi' myself so that's why I'm doin' it and finishin' it"* (Laura)

Successful treatment functioned as a means of stepping back from the PWID identity, and repairing the self-concept as a "good enough" or at least "un-defective" caregiver. For some, this was with a view to the possibility of recovering lost relationships with estranged children:

> *"I had it in my head tha' I get rid 'a the Hepatitis I come off the drugs I kick-start my life again eh an' I get … back into my son's life aswell"* (Matt)

Lisa speaks of the obligation and duty of care she feels towards her eight month old son in foster care. For Lisa, undertaking treatment acted as a proxy for giving care, as she could not do this in an immediate way:

> *"My son he's he's no' actually stayin' wi' me … so the way I seen it is if I end up no' well whose gonna look after him so I need to get myself better"* (Lisa)

Values:

Family and health were the two most salient values motivating participants:

> *"The only reason I wouldde do it is fer my kids if I never had anything else cos I've not got nothing else in m'life"* (Peter)

Parenting with HCV is a tiresome, weary task. Paranoia and hypervigilance characterised physical interactions with children, as many parents employed the strategy of limiting physical proximity to manage the perceived risk. This bodily separation precipitated a distressing sense of estrangement. Clearance was a means of obtaining normality as a caregiver: *"being able to take ma son out an' jus' do normal things wi' 'im"* (Laura). Participants were concerned about the impact of a shortened lifespan or poor health upon their family. Witnessing others visibly ill from HCV-related morbidity instilled an awareness of personal mortality which reinforced the motivation to complete treatment:

> *"What was important about getting treated?"*
> *... I've seen a few people die wi' cirrhosis 'a the liver yea an' it's not a very nice way to go... tha' was the reason"* (Sean)

Sean later hypothesises that taking action to engage in treatment would prevent dependency on his children in later life. This was not a universal motivator however, as some participants indicated little understanding of the medical complications of untreated HCV.

Response-ability and connection:

Participants intentionally prioritised treatment over other competing demands. To prevent missed doses medication was systematised and routinized into a stable regime. Treatment engagement was not only an act of autonomy but a manifestation of maturity and reciprocity, where the self, and others, are respected through consciously chosen action. Responsible self-care behaviour arose from a sense of reciprocity:

> *"Their attitude aye really nice people [the staff] like I say so .. felt like I'd be lettin' them down if I dinnae turn up"* (Jack)

Connection to a supportive interpersonal context (treatment trial staff, spouses, friends or children) provided a social context that supported positive treatment adherence. Availing of practical support was a manifestation of healthy reliance, which included assistance with logistic concerns such as access to the pharmacy. Emotional encouragement promoted resilience and commitment:

> *"My missus she was like tha' look stick in y'know you you could do it'"* (Mike)
> *"They (the nurses) encouraged us aye ... 'yer doin' well' ... 'keep goin' 'ken' ... an' sorta cheer us up a bit aswell"* (David)

Clearance provided permission to engage with others in a more intimate way, with *"nothing to hide"* (Gemma). The trial itself offered a means of being part of, rather than outside an in-group. There was a sense of belonging, connectedness and pro-social group identification. Matt identifies how he began to relate to the staff in a way that transcended traditional professional-service user roles. The culture of the centre mitigated the power imbalance between professional care provider and client, and promoted a sense of equity and equality. This was achieved through the use of humour, laughter and light-hearted dialogue:

> *"I think that's wha' their a lotta their remit is … they've got a buddy ethos … likes 'a you come it's buddy buddy it's no staff client"* (Matt)

Opportunity and purpose:

Completing treatment was a "goal", a source of achievement which produced feelings of relief, joy and success. The vouchers and fortified drinks were conceptualised as "rewards" which positively reinforced and incentivised attendance at appointments. In this way, treatment was a scarce opportunity to succeed at something, to be recognised and validated for the investment of effort.

For some, HCV treatment was part of moving on from drug addiction, and was a "kick start" to fulfil personal potential and lead a more meaningful life. Matt captures the paradox that stability in his living conditions allowed him to contemplate the future in a flexible way and enact value led behaviour through volunteering in the community:

> *"I'm layin' roots", "now I'm stayin' in one place I'm movin' forward"* (Matt)

In a world where PWID are accustomed to rejection and judgement, some expressed gratitude for this rare experience of being valued and cared for:

> *"I couldn' have asked for anything better for (than) wha' they've done f'ma (for me) 'ken because … it's easy enough for people to turn you away"* (Dean)

Discussion

Contextualising the Grounded Theory

This grounded theory proposes a developmentally informed, contextual framework for HCV treatment adherence. The socio-cultural context of the population, and the conditions of the trial emerged as an important feature of treatment adherence. Adherence is a dynamic process, whose underlying function, rather than form, should be understood. "Motivation" and "emotion" have the same conceptual and etiological origins meaning "to move"; this grounded

theory captures the role of human psychology in the reorientation from a stuck, marginalised position toward an expansive, valued life direction.

The social milieu of HCV is one of interpersonal deprivation and exclusion which is reinforced and perpetuated by societal institutions and the individuals who comprise these institutions (Cockersell, 2015). PWID identify with and are identified by the collective noun "junkies", conjugated from "junk": discarded articles that are considered useless or worthless. The conceptualisation of the HCV virus as "a dirty junkie's disease" not only echoes derogatory colloquialisms used to refer to PWID, but may also be a projection of internalised self-disgust and shame. Alienated, rejected mind-sets are shaped at the interface between the social and individual; as is the potential for behaviour change. The processes which precipitate and maintain adherence: hope, agency, autonomy, purpose and connection are scaffolded by good enough care that facilitates psychological safety. At the root of these qualities, secure relational bonding has a reparative impact on the effects of complex trauma, stigma and isolation, to enabling a sense of value and purpose to emerge, from which health behaviour change follows.

Findings concur with existing literature that posits the patient-provider relationship as a critical mechanism in treatment engagement and medication adherence (Evon, et al., 2015; Stewart, Mikocka-Walus, Harley, & Andrews, 2012). The need to be valued, to be heard, to belong, to achieve and to have meaning are considered universal and primal (Seager, Phipps, Murphy, & Barker, 2017). The care provided within the ERADICATE trial not only treated the HCV virus as a medical condition but also met the psychological needs of participants. When these needs were met sensitively and sufficiently, participants could expand their behavioural repertoire and demonstrate this in mature and responsible ways. The skill of staff was to interpret and respond to participants with compassion, authenticity and humanity. One interpretation is that the centre provided a physical and mental representation of a both a "safe haven" and "secure base", a point of stability and security where fears could be "housed" and contained. The outcome of this was development of agency, referring to participants' subjective awareness that they can initiate, execute, and control one's own actions in the world, and channel this into performing independent self-care behaviour. The fact of being part of a research trial may also have functioned as an in-group identity: participants were part of a bigger, meaningful unit that others regarded with respect. Under these conditions, participants could mobilise as autonomous agents, able to make flexible, intentional choices i.e. attending the drop-in clinic and sustaining a daily self-administered medication regime. Other studies also support the finding that HCV treatment adherence is strongly influenced by service accessibility, alongside the integration and coordination of healthcare services (Harris et al., 2013).

Previous qualitative studies have documented how negative cognitive evaluations, such as fear of side-effects or procedures can lead participants to avoid HCV treatment, whereas confidence in a cure promotes adherence (Sublette, Smith, George, McCaffery, & Douglas, 2015). Similarly, the Information-Motivation-Behaviour Model espoused by Evon, et al. (2015), places an emphasis on information-processing as a primary determinant of adherence behaviour. While this study shows that education can be supportive and empowering (e.g. challenging stigma by correcting assumptions among family members), the focus on the content rather than the context of knowledge provision is incomplete. Beyond intellectual appraisals, adherence behaviour encompasses deeper intrapsychic processes situated in a relational context. In this sample, confidence in the efficacy of the medication itself was variable and knowledge of the virus and side-effects were highly aversive, but did not trigger avoidance. From a developmental perspective, the receipt of transparent explanations of treatment and the setting of expectations relating to adherence may have served a regulatory and containing function for these participants, rather than what was said about the medicines per se. This would explain why, rather than being overwhelmed and immobilised by the guilt of contracting the virus, participants embraced their obligation and duty of care. Living with the risk of transmission to a child was a violation of the perceived role of a parent as a protector. This awareness enabled participants to tolerate side-effects with acceptance, in the service of what they truly valued: health and family. Paradoxically, increased self-efficacy scaffolds healthy, interdependent behaviour. The effective use of support from partners and family outwith the trial and centre is a sign of psychological maturity, marking a shift from the shame, isolation and vulnerability that characterised positive HCV status, towards effective help seeking. Despondent narratives of dirt, disgust and rejection pose a contrast to actual behaviour that demonstrated responsibility, worthiness and reciprocal connection. The provision of fortified drinks not only reinforced behaviour as a reward, but also symbolised the values underlining the trial, that PWID with HCV are deserving of care.

Strengths and Limitations

This study only recruited participants who had demonstrated positive adherence behaviour. The reported findings focus on sustained engagement rather than initial treatment uptake. This lends a quality of homogeneity and specificity to the sample, which has enabled the theory of adherence to emerge faithfully. This study has also uniquely captured the meaning of contingency management (receiving drinks and shopping vouchers for adherence behaviours) in the context of treatment engagement. While data was self-reported, liaison with the trial team facilitated verification of clinic activities and descriptions. This study did not recruit participants that had disengaged from treatment, as these participants were a small proportion of the whole cohort (<8%) and were lost to follow-up. The sample was therefore representative of the larger

trial group regarding positive adherence. However, this may reflect a limitation as the grounded theory may not be wholly applicable to PWID who are not engaged in any healthcare services. While a theoretical sampling method was employed, participants were recruited by staff who knew them previously from working within the Needle Exchange Clinic. This possibly increased the risk of sampling bias as staff members may have been more likely to approach certain participants for recruitment, depending on their attitude towards, and familiarly with different individuals. More males than females participated, however, this reflected the gender distribution of the full cohort. The findings of this study were generated from patients participating in a drug treatment trial based in the community, so may not be wholly transferable to other geographical locations or treatment settings. This study addresses the underrepresentation of the UK population in the existing literature. Future studies should seek to understand the situation of those who do not access healthcare.

Theoretical Implications and Recommendations

This study makes a unique contribution to the conceptual development of HCV treatment adherence among PWID. Compared to existing models of adherence, the data speaks to a different theoretical affiliation. The findings may linked to Attachment Theory (Bowlby, 1979) and the evolutionary principles underlying compassion focused therapeutic approaches to lend further coherence and robustness to the findings. The ontological conjecture arising from this study is that humans are innately resilient, relational beings who have evolved to form bonds with others in a social context. When the correct conditions and contingencies of compassion and care are in place, the innate propensity to learn and grow can manifest in adaptive and engaged behaviour, including treatment adherence.

Models such as the Information-Motivation-Behaviour Skills (IMB) Model of Adherence place information as the primary stimulus of behaviour change. This grounded theory places the innate drive and capacity to obtain care and affiliation at the heart of human motivation. This conceptualisation is made more robust by a developmental understanding of adherence and PWID as a population, given that the prevalence of childhood and adult trauma is higher among heroin users and unhoused populations (Wang et al., 2010). Sensitivity to the bio-psycho-social impact of abuse and neglect gives us a more complete understanding of the conditions that are more likely to be conducive to adherence behaviour in this group, beyond information giving. Human psychology is designed to respond to stimuli and integrate our perception into a narrative. When PWID are characterised as “chaotic”, there is a failure to appreciate what this may truly reflect: difficulty making sense of internal experience resulting in the absence of order, coherence and meaning. This is the outcome of not receiving good enough care in the earliest

days of life and while this precipitates states of isolation and disconnection, reparative care-giving experiences can facilitate new ways of relating to one's emotional and physical needs.

The grounded theory outlined here has utility in the field of HCV treatment adherence research as it can be used to develop quantitative studies of psychological variables. For example, the role of the care provider relationship in mediating or moderating adherence behaviour could be examined using standardised outcome measures. Additional qualitative research could seek to understand the perceptions of staff regarding engagement. Further research should seek to understand how the provision of good quality, sensitive, and compassionate care can be trained and preserved in this workforce.

Clinical Implications and Recommendations

This paper corresponds and responds to the conversation initiated by Harris and Rhodes (2016) using a qualitative approach to HCV treatment in the UK. Authors have expressed the "fundamental need for community based interventions" (Harris, M., Rhodes, 2016, p.86) in HCV treatment provision. This grounded theory concurs that community based, flexible, integrated harm reduction and social care services, alongside person-centred, continuous care are key to supporting sustained treatment engagement. For "treatment as prevention" to become a reality, individual and systemic factors need to be holistically addressed.

Conclusion

HCV treatment innovation has inspired declarations that the virus could be eliminated in the next 15 years (Watts, 2014). Regardless of how efficacious treatment becomes, the human condition is still subject to structural and psycho-social barriers (Harris et al., 2013). Alongside medication advances, policy and policy implementation need to progress in line with social justice values (Harris and Rhodes, 2016). Based on the current findings, it is recommended that HCV treatment providers prioritise two aspects of service provision: (1) optimising logistical and structural facilitators through community based treatment, and (2) protecting the interpersonal skills of staff as an essential human resource. Building relationships with vulnerable people takes time, energy and investment of emotional labour. This should be given due consideration in job planning and capacity forecasts for staff at the frontline of administering HCV treatment. Applied psychologists are well poised to provide enhanced understanding of HCV treatment adherence and working indirectly to support nursing staff in the service of optimising care for socially excluded populations.

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Authors' information

The lead author, CMB designed the study, completed data collection, coding, analysis and wrote the manuscript. CMB was undertaking doctoral study in Clinical Psychology and has an academic and clinical background in child and adolescent psychology. The second author, DG supervised this work, and supported the drafting of the manuscript, data analysis and interpretation.

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Chapter 2:

Factors associated with Staff Turnover in Substance Misuse: A Systematic Review

Carolyn Maeve Butler [ab,1], David Gillanders [a], Csilla Guylias [a], Kevin Power [b], and Kirsty Gillings [c]

[a] School of Health and Social Sciences, The University of Edinburgh, Teviot Place, Edinburgh, Scotland, UK, EH8 9AG.

[b] NHS Tayside Psychological Therapies Service, Dundee Health and Social Care Partnership, 15 Dudhope Terrace, Dundee, Scotland, UK, DD3 6HH.

[c] NHS Fife, Psychology Department, Stratheden Hospital, Cupar, Fife, Scotland, UK, KY15 5RR.

(for submission to Harm Reduction Journal see Appendix VIII)

[1] Corresponding postal address: NHS Tayside Psychological Therapies Service, Dundee Health and Social Care Partnership,15 Dudhope Terrace, Dundee, Scotland, UK, DD3 6HH. Tel: 01382 346 556; *E-mail address:* maeve.butler@nhs.net

Abstract:

Background: Staff turnover in substance misuse services has been established as a significant problem. A lack of workforce stability negatively impacts both clinical care and organisational management, as continuity of care is key to engaging complex client groups. Turnover process models highlight employee morale, mobility and intention to leave as salient aspects of turnover. This systematic review provides a narrative synthesis of quantitative studies to ascertain factors associated with actual staff turnover in substance misuse services.

Method: A search for peer reviewed journal articles from 1980 to 2016 was conducted using the following databases: PsychINFO, Medline, EMBASE and CINHAL. Studies were appraised according to eligibility and evaluated against 19 quality criteria. Appropriateness of design, methodological rigour, issues of bias and generalisability were assessed and reported on.

Results: Nine studies met inclusion criteria, reporting turnover among substance misuse counsellors, nurses and clinical supervisors. Factors that were associated with turnover included workforce characteristics (shorter tenure, staff having a history of substance misuse themselves), psycho-social variables (job satisfaction, relational skills) and organisational factors (job demand, prior turnover, and participation in management). Studies were considered to be of moderate methodological quality with limitations including: a lack of robust conceptualisation and measurement of constructs, poor integration and application of turnover process theory and a lack of generalisability to services outside the United States.

Conclusions: Interventions to prevent turnover are needed, and are likely to be enhanced by improving social support and job satisfaction within the workforce. The destination of leavers should be considered in order to contextualise departure decisions within the broader economic climate.

Keywords: Review, staff, nurses, counsellors, turnover, retention, substance misuse, organisation, job satisfaction.

7,493 words

Introduction

Scale of Turnover

Turnover is consistently posited as a major problem in substance misuse services (Eby & Rothrauff-Laschober, 2012; Garner et al., 2012; Laschober, Turner, & Eby, 2013). Workers in this field are embedded in highly strained delivery systems, typified by small capacity and heavy caseloads (Eby, Ph, Burk, & Maher, 2010; McLellan, Carise, & Kleber, 2003; McNulty, Oser, Johnson, Knudsen, & Roman, 2007). A quality and performance report of a UK based National Health Service (NHS) Trust in London found that, over a one year period, 2015-2016, addiction services had the highest staff turnover among 17 general, specialist mental health, and forensic services (Council of Governors, 2015). Annual rates of staff turnover have been recorded as high as 50% in the United States (McLellan et al., 2003).

Implications of Turnover

There is an increasing pressure to adopt evidence based practice (EBP) within the field of mental health and substance misuse. The implementation of empirically supported interventions requires services to both train and retain competent staff on long-term basis (Garner et al., 2012). A lack of workforce stability subverts efforts to achieve programme level change within substance misuse, for example, the integration of mental and physical healthcare (Friedmann, Lemon, Durkin, & D'Aunno, 2003). Turnover represents a poor return-on-investment regarding the resources spent on recruitment and training (Garner et al., 2012). The cost of nurse turnover has been estimated to be up to twice the salary of the nurse that left (McConnell, 1999). There may also be difficulties filling positions with suitably experienced and qualified staff (Gallon, Gabriel, & Knudsen, 2003). The efficiency of service provision is negatively affected, as capacity decreases, and demand remains the same, potentially leading to delays meeting statutory performance standards.

Indirect costs include decreased morale among remaining employees and increased stress due to higher caseloads (Johnson & Roman, 2002; Knight, Broome, Simpson, & Flynn, 2008). Turnover undermines stable, quality treatment provision and has been determined to have a harmful impact on client care in both private and public sector NHS settings (Ducharme, Knudsen, & Roman, 2008; Duffield, O'Brien-Pallas, Roche, & Catling-Paull, 2009). A UK-wide database of all suicides by people in contact with mental health services over a 12 month period, found that non-medical staff turnover (nurses, and other therapeutic staff), was significantly associated with suicide rates (Council of Governors, 2015). While the finding is not causal, and not specific to substance misuse services, the loss of a therapeutic relationship can have a significant and potentially serious impact on service-users. Conversely, continuity of care has

been linked to better clinical outcomes within the substance misuse population, including longer treatment engagement and retention (Lamb, Greenlick, & McCarty, 1998).

Models of Turnover

A conceptual review of turnover process models concluded that the literature contains three components: employee morale, employment mobility, and intentions to leave/stay (Steel & Lounsbury, 2009). Mobility and intention to leave are proposed to be based on perceptions of the job market, the objective availability of alternative opportunities, and cognitive appraisals of the desirability of moving. The push–pull model (Jackofsky, 1984), extends the ease-of-movement model (March & Simon, 1958), proposing that low performers are "pushed" out of the organization due to perceived threat of negative evaluation, and high performers are "pulled" out of the organization due to greater job alternatives. Lastly, employee morale, which incorporates job satisfaction has also been posited as a core mechanism in turnover theory for many decades (Steel & Lounsbury, 2009). Authors have argued that departure decisions should be understood within the broader interpersonal context of the workplace (Knight, Landrum, Becan, & Flynn, 2012). Therefore, variables which capture collective support are being explored alongside individual-level predictors (Garner & Hunter, 2013).

Current Review

The evidence base has demonstrated a shift from the study of turnover intentions, to actual turnover (Garner & Hunter, 2013). A focus on turnover intention alone is limited, as staff may want to leave their job, but do not act on this for an indefinite period, due to mitigating factors (e.g. loss of a social network of co-workers, benefits such as health insurance, fear of financial instability) (Eby et al., 2010; Kammeyer-Mueller, Wanberg, Glomb, & Ahlburg, 2005). Meta-analytic research has shown that the correlation between turnover intention or withdrawal cognitions, and actual voluntary turnover is just 0.45, and recommends that the terms are not used interchangeably (Tett & Meyer, 1993). It is widely assumed that involuntary (initiated by employer) turnover is less welcome for organisations compared to voluntary (initiated by employee) turnover, as higher performing individuals choose to leave (Eby et al., 2010; Laschober et al., 2013). Research also shows that when retention interventions are linked to the reasons why people leave their jobs, they tend to be more successful (Steel & Lounsbury, 2009). Therefore, the most pragmatic way of understanding turnover is by identifying variables associated with actual voluntary turnover. Based on the need to address the problem outlined, the current study used a systematic review approach to answer two questions: (1) how is staff turnover operationalised in the field of substance misuse? (2) what factors are associated with staff turnover in this field and what rationale is offered for these links?

Method

Search Strategy

The literature search was initially conducted in November 2016. To ascertain if a similar review had been conducted previously, the Cochrane Database of Abstracts of Reviews of Effective Practice and Organisation of Care was searched. This scoping search generated only one article loosely linked to the current topic, a systematic review of controlled studies assessing the effect of exit interviews to reduce staff turnover in healthcare (Webster & Flint, 2014). Searches were subsequently undertaken using PsychINFO (1987-2016), EMBASE (1980-2016), MEDLINE (1946-2016) and CINHAL (1937-2016) electronic databases, covering biomedical and psychological literature, including European and American peer reviewed journals. A time parameter was set from January 1980 to November 2016 to gather recent evidence in line with the aim of the review. To formulate the search string, terminology and common key words were adopted from other systematic reviews in the field (e.g. Van Boekel, Brouwers, Van Weeghel, & Garretsen, 2013). The population of interest was substance misuse staff, representing clinical personnel in general, and specific professions such as nursing and counselling ("staff" OR "employ*" OR "personnel" OR "team" OR "nurs*" OR "cousell*" OR "psych*" OR "social work*"). The second group of search terms described workplace settings, services for the substance misuse client group ("substance *use" OR "substance abuse" OR "substance use disorder" OR "alcohol addiction" OR "drug addiction" OR "opioid-dependent" OR "drug detox" OR "drug rehab*" OR "methadone maintenance" OR "harm reduction"). The last group of search terms comprised the outcome of actual staff turnover ("turnover" OR "retention"). A manual search of reference lists from the included articles was also used. To minimise publication bias, primary authors from included studies were approached. One was not contactable and of those who responded, no additional unpublished research was suggested. Searches were limited to studies published in English, as translation was not feasible.

Study Selection

Fig. 1 shows a flowchart of the selection process. In the first selection phase, titles of all articles were screened based on three conditions within the domains of title, abstract and keywords: (1) focus on substance misuse services, (2) actual staff turnover was the subject of the study and (3) factors associated with actual turnover were studied quantitatively. Any article that fulfilled at least two of these parameters or were ambiguous in one aspect, proceeded to the next selection phase. Thereafter, full text articles were reviewed.

Inclusion criteria

- Studies published in English, using a quantitative, or mixed method design (observational, cohort/cross-sectional, longitudinal).
- Subjects of the study are clinical professionals (nurses, counsellors, supervising clinicians) working in substance misuse services (alcohol or illicit drug treatment/detox, methadone maintenance, harm reduction).
- Studies primarily focussed on factors associated with actual staff turnover in substance misuse.
- Studies focussed on generating quantifiable empirical data to compute the strength and/or association of factors related to staff turnover in substance misuse.

Exclusion criteria

- Studies that are purely descriptive or theoretical.
- Studies using only qualitative methods, individual case studies or treatment studies.
- Studies of turnover in services that may or may not serve a substance misuse population (general adult mental health or forensic services) or unspecified.
- Studies focussing on turnover intention, burnout, emotional exhaustion or related constructs as outcomes, but do not consider actual turnover.
- Subjects of the study are administrative, or non-clinical staff, or clients.

Table 1: Inclusion/Exclusion Criteria

Data Extraction and Synthesis

Data was extracted on each study's aims and hypotheses, setting and characteristics of study population, sample size, study design, outcomes and measurement, and main results or conclusions (Table 4). Initially, the data extraction protocol was pilot-tested with two randomly selected studies, and refined accordingly. The first author (C.M.B.) extracted the data from selected studies and implemented the quality assessment tool. Reporting followed internationally accepted guidelines for producing systematic reviews as outlined by the Centre for Reviews and Dissemination (CRD), The University of York.

Quality Assessment

The current review used a checklist of 19 item quality criteria identified *a priori* to assess studies. In line with CRD recommendations quality criteria that are relevant and specific the current research question were employed. Issues of design, operationalisation of variables, reliability and validity of measures, representativeness and generalisability were considered (www.york.ac.uk/inst/crd/), the themes of which are summarised in Table 2. Each paper was rated on each item in accordance with Scottish Intercollegiate Guidance Network ratings of methodological quality. A 2 or 3 points based scale, depending on the relative importance of the specific item (for full description see Appendix VI). Outcome ratings were allocated as follows: "well covered" (3 points), "adequately covered" (2 points), "poorly addressed" (1 point), "not addressed / reported" (0 points) or "not applicable" (NA) (see Table 5). To ensure reliability,

quality assessment was conducted independently by a second reviewer (C.G) on a sample of studies (N=4; 44%). There was exact agreement on 78% (59/76) quality ratings, with a small amount of variance, with a difference of 2 points on 3% of items (3/76). Discrepancies in quality ratings were resolved via discussion and reviewing the original articles until a consensus was reached. A narrative synthesis of findings was also developed. The terms and definitions used in the original studies were used.

- Rationale and objectives: how clearly is the purpose of the study stated, including research question(s) and/or hypotheses?
- Design: how well does the methodology address the research question(s), how clearly is the study setting (service provision or structure of the substance misuse facility) and recruitment described?
- Variables: how clearly are constructs operationalised, how is the outcome variable (staff turnover) calculated?
- Reliability and validity of measures: how clearly is the data source described and is data cross-referenced if appropriate (e.g. if gathered retrospectively from an internal database), how reliable and valid are the outcome measures used?
- Descriptive data: how clearly is the sample described (e.g. tenure, recovery status of staff), is the sample representative of the population being studied based on their characteristics and response rate?
- Outcome data: how clear and appropriate are the statistical analysis used, is a power calculation reported?
- Treatment of confounds: have confounding variables (e.g. staff tenure) been controlled for?
- Completeness of data: how clearly have attrition and missing data been reported on, accounted for and handled to minimise bias?
- Interpretation and generalisability: how clear and cautious are the results in the context of limitations and existing evidence, does the data justify the conclusions drawn?
- Funding: are funding sources acknowledged, alongside their role if applicable, are ethical issues stated and addressed if applicable?

Table 2: Summary of Quality Indicators

Results

Search Results

The database search yielded 507 potentially relevant citations. Following de-duplication (n=46), a further 430 articles were removed after the first selection phase of screening the title and abstract. Therefore, 28 citations proceeded to the next stage where full text articles were examined leading to the final inclusion of 9 studies which met full inclusion criteria. This included one article which was sourced from a reference list (see Fig. 1).

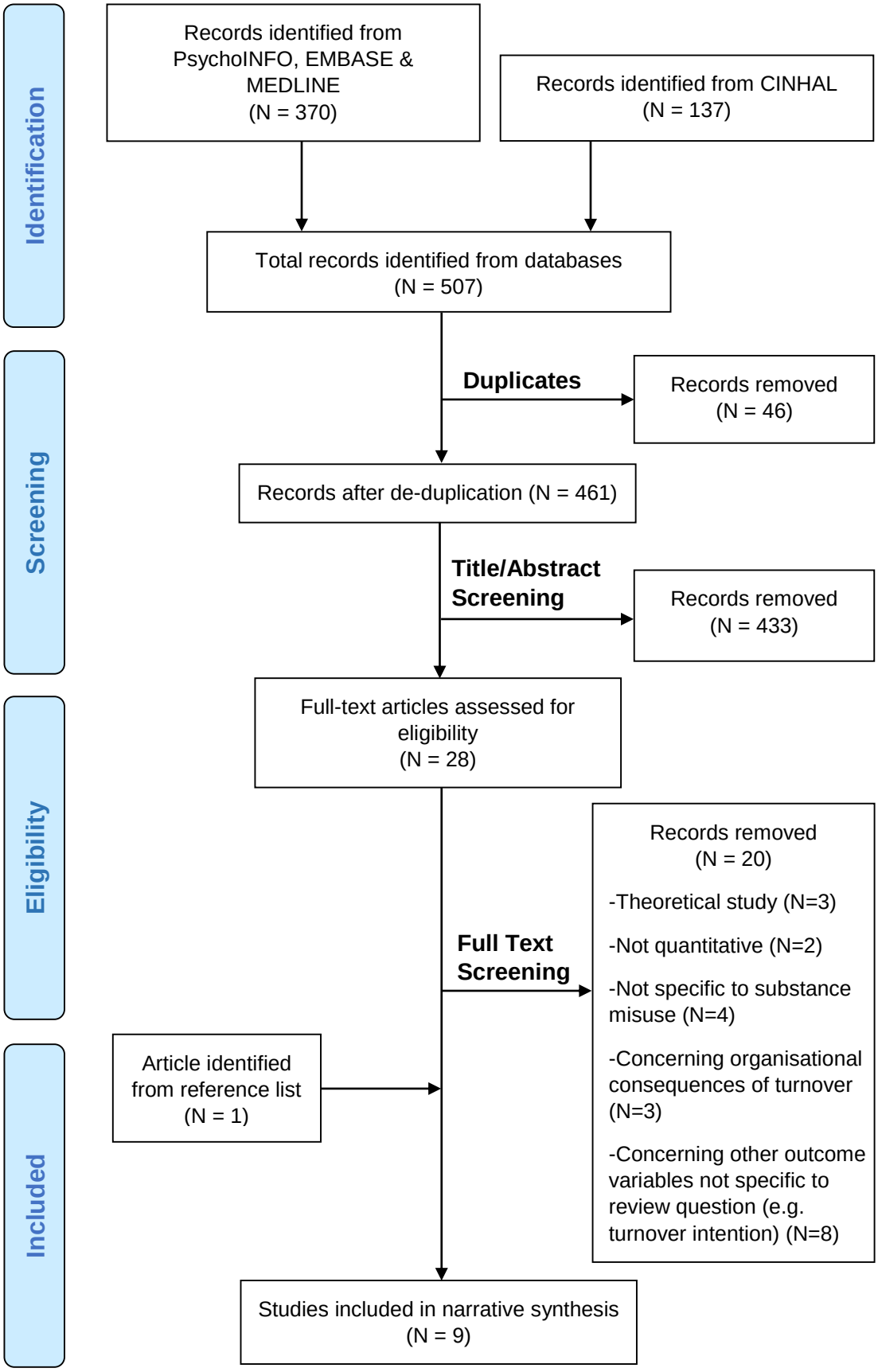

Figure 1: Search Strategy

Characteristics of Included Studies

Data was collected from a large number of substance misuse treatment programmes ranging from a sample of 25 outpatient community based substance abuse treatment facilities (Knight et al., 2012) to 217 private-sector alcohol and drug abuse treatment centres the majority of which were hospital based (McNulty et al., 2007). Seven were adult services, and two were adolescent facilities (Garner et al., 2012; 2013). Most programmes were situated within community based outpatient facilities. One study specified that staff had inpatient duties (Laschober et al., 2013). Descriptions of setting (e.g. organisation structure and service provision), location and recruitment method (e.g. periods of recruitment, follow-up, and data collection) were generally clear and appropriate across studies.

Seven studies looked at substance misuse counsellor turnover, one focussed specifically on nurses (Knudsen et al., 2011) and one on counsellor supervisor turnover (Knight, Broome, Edwards, & Flynn, 2011). Just one study stated explicitly that counsellors had direct therapeutic contact with clients individually or in a group (Laschober et al., 2013). In the sampled studies, the majority of staff were middle-aged Caucasian females, with an average age ranging from 35-47 years old. The majority of staff recruited across studies were highly educated to Master's degree (>40% across studies) or at least Bachelor's degree level, and had a per annum salary of between $30-34,000 (conversion is equivalent to experienced drug and alcohol workers in the UK). Four papers described that that the majority of staff sampled had 5+ years substance misuse counselling experience (Knight et al., 2011; 2012). Regarding tenure, only one study described that 42% of counsellors who had left their organisation had been in post for <1 year at the time of departure (Knight et al., 2012). The frequency of counsellors described as "in recovery" from personal substance dependence, ranged widely including rates of 5% (Garner & Hunter, 2013), 37% (McNulty et al., 2007) and 61% .

Author Year *Country*	**Primary Aim**	**Sample (N) Gender (% female) Mean age in years (SD)**	**Setting**	**Design** **Follow-up Period (months)**	**Outcome measures**	**Turn-over Rate (12 m)**	**Main Findings**
Laschober et al., (2013) *USA*	Investigated relationship between job performance (task performance, relational performance, organisational citizen behaviours-Individual, organisational citizen behaviours-organisation) and actual turnover.	440 matched counsellor-supervisor dyads. Counsellors: 63.64% 43.4 (±11.93)	26 treatment facilities	Cross-sectional survey Between groups 12	*Task performance* - 20-item scale* *Relational performance* – Eby et al., (2008) 7-item scale. *Organisational citizenship behaviours* - Williams and Anderson's (1991) 7-item scale.	23%	No difference in task performance between voluntary leavers and those who stay. Both voluntarily and involuntarily leavers were lower in relational performance than stayers. Both higher and lower levels of individual organisational citizenship behaviour was related to voluntary turnover.
Garner & Hunter, (2013) *USA*	Investigated psychological climate (supervisor support, co-worker support, role overload, role clarity, job challenge/autonomy) and work attitude (job satisfaction, pay satisfaction, benefit satisfaction, turnover intention, job involvement) as predictors of turnover at 4 time periods.	105 treatment staff 73% 36 (±11)	29 treatment orgs. for adolescents	Cross-sectional survey 4-6, 7-9, 10-12, 13-18.	*Psychological Climate Questionnaire Organisational Readiness for Change Instrument* (organisational domain) *Minnesota Satisfaction Questionnaire Pay Satisfaction Questionnaire* (Heneman & Schwab, 1985) *Job Involvement Scale* (Reeve & Smith, 2001) *Turnover intentions* – scale*	23%^	Within the construct of work attitude, job satisfaction, turnover intention and job involvement were found to be significantly associated with turnover. More positive psychological climate was predictive of more positive work attitude (β=0.87 ρ<.001). Work attitude fully mediated the relationship between psychological climate and turnover (hOR=0.95; ρ=.95) Together psychological climate and work attitudes explained 16% of the variance in turnover.
Garner et al., (2012) *USA*	Investigated organisational factors (programme needs, staff attitudes, organisational climate, job attitudes and workplace	121 counsellors 35.2 (±10.7), 73.6%	34 community-based treatment orgs. for adolescents	Cross-sectional survey 6, 9, 12	*Survey of Organisational Functioning* (SOF) – (Broome, Knight, Edward, & Flynn, 2009)	31%	The odds of transitioning to the not employed/not EBP-competent status, were significantly higher for males (OR=2.94) and greater perceived programme needs (OR=1.19), and burnout (OR=1.13). Odds were

	practices) as predictors of competence and turnover status at 3 time points post-training in an evidenced based model.						significantly lower for staff reporting higher levels of mission (OR=0.86), satisfaction (OR = 0.88), director leadership (OR=0.90), and collective responsibility (OR=0.90). Programme needs was the only predictor that was significantly linked to transition to not employed/not EBP-competent at 12 months (ρ =.018 <.05).
Eby et al., (2012) *USA*	Investigated counsellor perceptions of the organizational environment (procedural justice, distributive justice, perceived organizational support, and job satisfaction) and clinical supervisor leadership effectiveness (relationship quality, in-role performance, extra-role performance) as predictors of voluntary turnover over time.	598 counsellors 42.95 64%	26 community based orgs.	Cross-sectional survey 24, 36, 48	*Distributive justice* - Moorman's (1991) four-item scale. *Procedural justice* - Niehoff and Moorman's (1993) six-item scale. *Perceived organizational support* - Eisenberger, Cummings, Armeli, and Lynch's (1997) eight-item scale. *Job satisfaction* - Smith's (1976) six-item scale *Relationship quality* - Allen and Eby's (2003) 4-item scale. *Supervisors' extra-role behaviours* - Williams and Anderson's (1991) 7-item scale. Supervisors' in-role performance - 14-item scale*	25% (at 24m)	Counsellors with higher perceived procedural justice, distributive justice and job satisfaction were 14.7%, 18.2% and 22.8% less likely to leave voluntarily over the next 3 years than other counsellors respectively. Counsellors with more favourable perceptions of the organizational environment are between 13.8% and 22.8% less likely to turnover. None of the leadership effectiveness variables were significant.

Knight et al., (2012) *USA*	Investigated how perceived programme needs, change orientation, job attitudes, stress, burnout, satisfaction relate to actual turnover.	206 counsellors 47.23 (±11.23), 66%	25 OP SA treatment progs.	Cross-sectional Survey 12	*SOF*	No rate N=52 left	Programme needs x change orientation interaction (t=–3.03, ρ<.01) was a significant predictor of voluntary turnover, as were tenure (t=–1.90, ρ<.05), satisfaction (t= –2.23, ρ<.05). Staff who left voluntarily reported lower change orientation, (t= 2.34, ρ<.05), and lower satisfaction, (t=3.13, ρ<.01), compared with staff who stayed.
Knight et al., (2011) *USA*	Investigated how job attitudes, burnout, satisfaction, director leadership and organisational structure (service approach, parent affiliation, ownership status, criminal justice and dually diagnosed clients, caseload no. and no. counselling hours per client) influence turnover among supervisors.	532 staff 46 (±10.78) 61%	90 OP SA treatment progs.	Cross-sectional survey 12	*Survey of Structure and Operations* (SSO) - (Knight et al., 2008) *SOF*	33%	33% of programmes reported change in supervisor within 12 months. Programmes affiliated with a parent organisation had 4 times the turnover of those not affiliated with a larger body (OR=4.45). Parent affiliation and satisfaction were significant predictors after controlling for structure measures and director leadership (p<.05). Satisfaction is a marginally significant predictor of turnover in programmes with prior supervisory turnover (r=-0.23, p=0.08).
Knudsen et al., (2011) *USA*	Retrospectively investigated how organisational characteristics relate to nurse turnover and difficulty filing vacant positions.	215 admin. staff/ directors. Other not described.	122 community based treatment progs.	Cross sectional survey 12	Structured pro-forma* capturing hospital location, for profit, accreditation status, offers opioid treatment, offers residential treatment, adolescent-only treatment, programme operations.	15%^^	A vacant nursing position took 2 months to fill (M=74.4 days, S.D=61.6). Nurse turnover was positively associated with offering residential treatment and reduced operations within the last two years (ρ <.05) and negatively associated with adolescent only treatment services (ρ <.05) and hospital based programmes (ρ <.01).

Eby et al., (2010) *USA*	Retrospectively investigated reasons for annual turnover among full-time counsellors and supervisors.	739 counsellors 68% 40 188 supervisors 53% 43	27 community based treatment orgs.	Cross-sectional survey & Interview 12	Structured pro-forma* Qualitative – exploratory; structured interviews with a subset of former employees	25% & 14% (s/vis)	Most common reason for counsellor & supervisor turnover was a new job opportunity (27.3%, 29.5% respectively). Personal reasons for voluntary counsellor and supervisor turnover included: relocation, personal health, return to school and retirement. 36% of counsellors who left the organisation also left the field completely.
McNulty et al., (2007) *USA*	Investigated counsellor-management (participatory management and organisational commitment), centre characteristics (hospital based, for profit, capacity, salary, prior turnover), workforce composition (gender, ethnicity, education, certification and recovery status) and client-counsellor relations (clients in relapse, court-mandated clients, Medicaid clients and managed care referrals) as predictors of turnover.	Total N staff not stated. 57% Mean age not described.	217 private-sector alcohol and drug abuse treatment centres.	Cross-sectional survey 12	*Participatory management* - Niehoff and Moorman's (1993) six-item scale. *Organisational commitment* - 4-item scale developed for the study. All other variables - structured pro-forma*	16%^^	Prior turnover is positively related to subsequent turnover until the prior turnover rate reaches about 48%. 34% of the variance in turnover rates, was explained by a model including indicators of centre and workforce characteristics. Percent of counsellors in recovery has the strongest effect on turnover (β = .301), percent certified (β = –.239), centre capacity (β =.217), prior turnover (.230, –.170), percent minority (β = –.213), profit status (.192), percent managed care referrals (β = –.168), percent female (β =.152), and organizational commitment (β = –.153).

Table 3: Summary of Study Characteristics

*Scale / tool was developed for the study ^Mix of voluntary and involuntary leavers ^^Average annualised rate

Factors Associated with Turnover

Workforce Characteristics

Two studies recorded personal reasons for voluntary turnover including retirement, relocation, return to education, family concerns and changing career (Eby et al., 2010; Knight et al., 2012). Eby et al. (2010) reported that "new job/other opportunity" was the most common self-reported reason for both counsellor and clinical supervisor turnover. Regarding tenure in an organisation, those who have been employed for fewer years are more likely to turnover voluntarily ($t=-1.98$, $\rho<.05$ (Knight et al., 2012). Counsellor certification status, years of experience in substance misuse counselling, or salary were not found to be linked to voluntary turnover (Garner & Hunter, 2013; Laschober et al., 2013). Counsellors with their own previous history of substance misuse, who were now in recovery ('recovery status') were more likely to leave their jobs. Counsellor recovery status was the strongest individual predictor of turnover across different regression models (McNulty et al., 2007).

Performance

Helping behaviour towards colleagues had a curvilinear influence on the relationship between job performance and voluntary turnover (Laschober et al., 2013). Laschober et al. (2013) found that counsellors who were rated lower by their supervisors on their relational performance (e.g. being considerate of, and responsive to colleagues) were more likely to turnover voluntarily compared to their colleagues that remained employed, where an Odds Ratio (OR) of >1 indicates a negative relationship ($OR=0.69$, $\rho<0.01$). Lower task performance was significantly related to involuntary, but not voluntary staff turnover. Regarding strategies to upskill the workforce, 31% of staff who completed in house training in evidence based practice were not employed one year after the event. However, this study did not differentiate between voluntary and involuntary turnover, and did not provide a comparison of turnover rates among staff who did not receive training (Garner et al., 2012).

Psycho-social variables

Job Satisfaction

Job satisfaction was the most consistent factor associated with staff turnover, and was found to be a significant predictor in four studies where it was included in the final multi-variate analysis (Eby & Rothrauff-Laschober, 2012; Garner et al., 2012; Knight et al., 2011, 2012). Counsellors with higher job satisfaction were 22.8% less likely to voluntarily leave the organisation within 3 years ($\beta=-0.26$, $\rho<.01$) when race, gender, tenure in the organisation and certification level was controlled for (Eby & Rothrauff-Laschober, 2012). In another study, after controlling for job attitudes, staff demographics, and organisational factors (i.e. parent

affiliation, service approach), lower job satisfaction was a significant predictor of turnover (t=-2.23 ρ<.05) (Knight et al., 2012).

Work Attitude

Using a mediational model of analysis, Garner and Hunter (2013) concluded that work attitude (including job, pay and benefit satisfaction, intentions to quit and job involvement) fully mediated the relationship between "psychological climate" and turnover. The sample was conservative (N=95) and no power calculation was described.

Organisational factors

A model combining counsellor-management relations, centre characteristics, and workforce composition explained 32% of the variance in voluntary counsellor turnover (McNulty et al., 2007). Workforce composition (i.e. frequency of certified counsellors, counsellors in recovery) and centre characteristics (i.e. greater capacity, prior turnover and for-profit status) explained the effects of the latter variables on turnover (McNulty & Oser, 2007). Higher participatory management and organisational commitment were related to lower voluntary turnover (McNulty et al., 2007). Similarly, higher perceived organisational support, but not relationship quality with a clinical supervisor, protects against staff turnover; counsellors who felt greater levels of support were 13.8% less likely to leave their job over the next 3 years (β=-0.15, ρ<.05) (Eby & Rothrauff-Laschober, 2012).

Job demands

Using a subset of a larger sample, Knight et al. (2012) reported that the likelihood of staff turnover was higher for those who perceived higher programme needs (or job demands), when organisational change orientation was low. The latter variable communicates the willingness and flexibility of an organisation to adjust and adapt to demands. The association remained significant after controlling for programme characteristics, staff demographics and ratings of stress, burnout and satisfaction. Job demands was the only variable that remained a significant predictor of staff turnover at 6, 9, and 12 month follow-up, where higher demands precipitated greater turnover (OR=1.16, ρ<0.05) (Garner et al., 2012). McNulty et al. (2007) assessed features of the client group, including relapsing clients, court-mandated, and low-income clients. Only managed care referrals were significantly negatively associated with voluntary turnover (β=-0.168 ρ<.01). The specific needs of these cases were not described, however it is stated that these clients are generally employed, indicating a greater degree of occupational functioning. Residential treatment (β=0.508, ρ<.05) and services that had 'reduced operations' in the previous 2 years (β=0.412, ρ<.05) (Knudsen et al., 2011) were both positively associated with turnover among nursing staff, though the exact meaning of the latter variable was not described.

Methodological Characteristics and Quality of Included Studies

Table 5 provides ratings for each of the studies on the 19 quality criteria. This scale does not provide a basis for exact comparison, but does act as an indication of relative methodological strengths and weaknesses. The systematic rating of studies suggests that Laschober et al. (2013) and Knight et al. (2012) were the methodologically strongest studies with the greatest number of adequately and well covered criteria. These two studies clearly addressed the relationship between variables, using an appropriate design and cross-referenced data source. Overall, the quality of reviewed studies was reasonable, meaning that at least half of criteria were well or adequately covered. Limitations regarding the reliability of measures and issues of representativeness may have modestly affected the findings or conclusions.

Design

Most studies used exploratory, observational designs. One of the methodologically strongest studies (Laschober et al., 2013) uniquely used a design comparing groups of those who stayed and those who left voluntarily and involuntarily. Garner et al. (2012) also compared groups but did not distinguish voluntary from involuntary leavers. Six were original studies and 3 studies reported the secondary analyses of a larger dataset. Subsequent studies examined a different research question using the same dataset (Eby et al., 2010, 2012; Garner et al., 2012, 2013) or reported counsellor and supervisor turnover separately (Knight et al., 2011, 2012). Studies suffered from a lack of robust construct reliability and validity, as outcome variables were at times poorly described and vague (e.g. "psychological climate", or "individual organisational citizenship behaviour" or "reduced operations"). The measures used across studies varied, but there were some commonalities. Three studies (Garner et al., 2012; Knight et al., 2011, 2012) used the Survey of Organizational Functioning (SOF), which has 129 items. As this measure was used in a number of studies, the psychometric properties were reviewed independently. The SOF is an expanded version of the Organizational Readiness for Change (ORC) instrument (Lehman, Greener, & Simpson, 2002), with the addition of a job attitude scale measuring perceptions of leadership, job satisfaction, and burnout (Broome, Knight, Edward, & Flynn, 2009). The development of the original measure, the ORC, was not supported by a confirmatory factor analysis (CFA) and five of the eighteen scales demonstrated questionable internal consistency. No validation studies for the SOF have been published to date. The psychometric properties of this tool make findings based on the ORC, and the revised SOF measure highly tentative. Three studies developed their own scales for the purpose of measuring task performance (Laschober et al., 2013), in-role job performance (Eby & Rothrauff-Laschober, 2012), psychological climate and work attitude (Garner & Hunter, 2013). While development was described and evidence of

validity was demonstrated with an acceptable alpha co-efficient ($\alpha<0.70$), the reliability of measures was not determined by CFA (DeVillis, 2012).

Representativeness

All studies were affiliated with large-scale evaluations of substance treatment facilities across the United States, including a combination of private and public facilities. Three studies only included organisations that were affiliated with the National Institute on Drug Abuse's Clinical Trials Network (Eby et al., 2010; Eby & Rothrauff-Laschober, 2012; Knudsen et al., 2011). While this does not constitute a random sample, one study (Eby et al., 2010) compared the characteristics of their sample to two nationally representative samples of substance misuse treatment facilities (see Ducharme, Knudsen, & Roman, 2008) and found that they were similar in terms of representations of age, gender, education level and certification. Other indications of representativeness (quality criteria: 11, 14, 15) were generally poorly, or not addressed by studies. The studies that were rated higher on methodological quality reported response rate, missing data and attrition, and contextualised these aspects in terms generalisability.

Criteria No.→ PAPER ↓	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Overall Quality Grading
Laschober et al., (2013)																				Good
Garner & Hunter, (2013)																				Reasonable
Garner et al., (2012)																				Reasonable
Eby et al., (2012)																				Reasonable
Knight et al., (2012)																				Good
Knight et al., (2011)																				Reasonable
Knudsen et al., (2011)																				Limited
Eby et al., (2010)								NA		NA		NA	NA							Limited
McNulty et al., (2007)																				Reasonable

Table 5: Ratings of Study Quality

1. Statement of purpose, 2. Rationale & objectives, 3. Design, 4. Setting & recruitment, 5. Data source, 6. Variables, 7. Reliability of measures, 8. Statistical methods, 9. Descriptive data, 10. Power of sample size, 11. Representativeness, 12. Outcome data, 13. Confounds, 14. Attrition, 15. Missing data, 16. Key results, 17. Limitations, 18. Interpretation & generalisability, 19. Funding & Acknowledgements

Well Covered	Adequately Covered	Poorly Addressed	Not addressed/reported	NA – Not applicable

Operationalisation of the Outcome Variable

The measurement of turnover was consistent but not wholly uniform across studies. Five studies used a standard formula for establishing turnover, which was operationalised as a percentage (the total number of individual staff that had left the organisation, during a specified period of time, divided by the total number of individual staff employed at a baseline time point). Two studies reported the actual, raw number of counsellors (Knight et al., 2012) and supervisors (Knight et al., 2011) who had left, rather than expressing turnover as a rate. Two studies calculated a less valid measure of turnover, in the form of an average annualised rate (Knudsen et al., 2011; McNulty et al., 2007). McNulty et al. (2007) based the turnover rate on a different sample (obtained 2000-2001) to the sample used to generate predictor data (obtained 1997-1998). Two studies did not distinguish between voluntary (initiated by staff member) and involuntary turnover (contract terminated by the organisation/employer) (Garner et al., 2012; Knight et al., 2011), indicating a significant limitation to comparison with other studies as the factors precipitating involuntary turnover are typically different (e.g. dismissal for misconduct).

Source of Data

Source of data was consistent across studies, where employment status of individual employees was commonly based on information provided by directors, managers, clinical supervisors or using HR/administrative records (exit interview contained in the employees personnel file) (e.g. Eby, Ph, Burk, & Maher, 2010). This method has been critiqued for accuracy, depending on the quality of internal record keeping (Eby et al., 2010). Retrospective or self-report data may also be subject to bias where attributions for turnover may be influenced by social desirability or legal diplomacy (Eby et al., 2010). In one study (Laschober et al., 2013) data on job performance was compiled from the evaluation of supervisors of counsellors they worked with. which may have influenced estimates of job performance. Moreover, supervisors completed questionnaires for a range of between 1-9 counsellors, indicating a risk of survey fatigue. Efforts have been made to check and validate data collected from organisation management by triangulating data collection. Studies that scored more highly on the quality criteria (see Table 5) cross-referenced their findings by conducting exit interviews with people who had left the organisation (e.g. Eby, Ph, Burk, & Maher, 2010; Laschober, Turner, & Eby, 2013). All studies provided financial reimbursement to organisations to compensate for the time required to provide data, potentially enhancing the accuracy of the data collected.

Discussion

Staff turnover in substance misuse is an extensive and concerning phenomenon. In the studies reviewed, between 23% (Laschober et al., 2013) to 31% (Garner et al., 2012) of the

workforce had left their current employment over a 12 month period. It is difficult to remain in a field that is characterised by poor pay, low status and emotionally exhausting work on a long-term basis (Eby & Rothrauff-Laschober, 2012). Findings show that factors other than salary or clinical complexity were more robust precipitants of turnover. The specific factors that were associated with turnover included workforce characteristics (shorter tenure, recovery status), psycho-social variables (job satisfaction, relational performance) and organisational factors (job demand, prior turnover, and participation in management). The dynamic interplay between the organisational and individual context forms a thematic thread throughout the studies reviewed. Findings should be interpreted within the methodological limitations of existing research.

Factors Associated with Turnover

Findings are consistent with meta-analytic research in organisational psychology which posits job satisfaction as one of the best proximal precursors of staff turnover (Griffeth, Hom, & Gaertner, 2000; Steel & Lounsbury, 2009). Job satisfaction has been conceptualised as a function of the employee unit; an organisational attribute, rather than a quality of an individual (McNulty et al., 2007). McNulty et al. (2007) have argued for the development of multilevel models that situate turnover behaviour in a social context, which recognises how the individual behaviour is embedded within, and potentially cued by systemic triggers. Organisational dynamics and individual decision-making influence each other synergistically (Knight et al., 2011). Having an effective clinical supervisor was not enough to offset turnover among counsellors indicating, that collective relationships rather than specific dyads, may be more influential. Similarly, even when employees are committed to the organisation and feel engaged with management, prior turnover explained the effect of counsellor-management relations on turnover (McNulty et al., 2007).

Both lower and higher levels of relational performance were related to voluntary turnover (Laschober et al., 2013). Employees demonstrating higher levels of helping behaviour toward colleagues may precipitate additional interpersonal burden, increasing the risk of burnout (Laschober et al., 2013). Lower levels of support for others was attributed to a lack of person-environment fit. Authors hypothesise that in caring professions, "going the extra mile" to help colleagues is an implicit expectation among peers. The absence of this behaviour may indicate interpersonal difficulties or unsupportive work relationships, which may feed into voluntary turnover. Task performance was not significantly higher among those who left the organisation, disproving theoretical supposition that higher performers are "pulled" into better jobs as suggested by Jackofsky's push-pull model (1984).

Structural features of a service, including greater centre capacity and affiliation with a larger parent body were more strongly associated with turnover than characteristics of the

population. Downsizing in residential settings may lead to changes in staff work patterns, including more anti-social shifts, or reduced hours, potentially making employment financially unviable for some employees (Knudsen et al., 2011). Indicators of client complexity were generally not found to be associated with turnover (McNulty et al., 2007). This finding may be considered counter-intuitive as injecting drug users can demonstrate high risk, challenging behaviour which is linked to higher stress and lower job satisfaction in staff (von Hippel, Brener, & von Hippel, 2008). This supports the conclusion that decisions to leave were based factors outwith features of the client population (Eby et al., 2010).

Strengths and Limitations of Review

Publication bias was managed by corresponding with authors of all included studies to included unpublished literature. Subjective bias in the rating of methodological quality was minimised by establishing high level of inter-rater reliability between independent reviewers. The review was limited to studies published in English. Some relevant databases were not included and a set combination of search terms were employed. To minimise heterogeneity of studies, strict inclusion and exclusion criteria were applied, such as limiting included studies to those that reported actual turnover rather than turnover intention, though this demarcation affords greater specificity and pragmatism to the review findings. Certain study designs (e.g. qualitative work, treatment trials) were also excluded. Such criteria may present a limitation to the scope of the search strategy by potentially excluding relevant studies.

Clinical Implications

Empirical evidence supporting the importance of job satisfaction, offers direction in developing interventions to promote workforce retention in substance misuse (Knudsen et al., 2011). Job satisfaction can be understood as, "feeling genuinely cared for, valued and supported by the organization … by meeting needs for approval, esteem, and *community* at work" (Eisenberger, Huntington, Hutchison, & Sowa, 1986). Counsellors are less likely to leave a work setting with high job demands, if they feel the organisation as a whole is orientated towards change (Knight et al., 2012). A culture of openness and flexibility may therefore protect against staff turnover by promoting prosocial engagement, belonging and connectedness thereby enhancing overall job satisfaction. These values should be articulated in policy, as a basis for communication and conflict resolution protocols and integrated into the induction of new employees (Knight et al., 2012). An intervention that involved acceptance skills and public declaration of values among staff has been found to have a superior positive impact on burnout among substance misuse counsellors, compared to multicultural training, at 3 month follow up (Hayes et al., 2004). Other suggestions for improving job satisfaction include greater participation in decision-making (e.g. managing capacity), an appropriate level of freedom and

autonomy in daily clinical work, and support for professional development through the provision of frequent, and positive feedback and recognition of performance (Eby & Rothrauff-Laschober, 2012). In order to maximise the long-term, sustained implementation of evidence based practice, interventions that support collective job satisfaction should be considered alongside changes to practice (Garner et al., 2012). To counteract the potentially negative impact of job demands on counsellors working in substance misuse, Knight et al. (2012) advocate for the allocation of resources to promote social support and affirm a culture of connection and co-operation. Eby et al. (2010) advocate team building workshops to enhance relationships. Leadership effectiveness should also be monitored at a managerial level, but rather than prioritising clinical and/or administrative competence, supervisors should be rewarded for their interpersonal skill (Eby et al., 2010). Staff may voluntarily leave the workplace due to degenerative physical illness, trainee counsellors rotating work placements, and family obligations such as parental leave (Eby et al., 2010), the latter of which may be particularly relevant to a largely middle-aged female substance misuse workforce. An organisational policy or protocol that includes exit interviews would help to clarify salient circumstantial factors that lead to turnover (Webster & Flint, 2014).

Theoretical Recommendations

There are several ways in which the study of staff turnover in substance misuse services can progress:

Measurement and Design

Existing evidence has scarcely moved beyond correlational models of analysis which do not demonstrate causality between variables. The poor quality of measures (e.g. the SOF) used to assess factors associated with staff turnover is also a drawback. Future studies should examine psychological variables such as stress, burnout and job satisfaction using standardised, valid and reliable measures to increase methodological quality, e.g. the Maslach Burnout Inventory (Maslach & Jackson, 1981).

Application of Theory

Ease of mobility and turnover intention are two constructs common in turnover process models (Steel and Lounsbury, 2009). The inclusion of studies that examined actual staff turnover is a methodological strength of this review, surprisingly however, the studies reviewed did not explicitly investigate the relationship between turnover intention and actual turnover. Empirical studies in this field would be more robust if they were more closely linked to turnover theory. The objective availability and subjective perception of alternative opportunities within and outside of the organisation could also be examined further (Knudsen et al., 2011). For a

portion of staff who voluntarily turnover, ease of transition to other facilities via intra-organisational transfer, or availability of alternative work will have been influential (Garner and Hunter, 2013). Increased focus on the destination of leavers would address this gap. Exploration of external factors and personal circumstance which lead to turnover would support the development of the field (Steel & Lounsbury, 2009).

Directions for Future Research

Geo-centrism currently limits the generalisability of findings due to differences in how substance misuse services are organised and funded in different countries. Turnover research based in healthcare systems that are publicly funded would enrich the field. Secondly, three authors, Dr. Bryan Garner, Dr. Lillian Eby and Dr. Danica Knight dominate the field of staff turnover in substance misuse. While an evidence base that is produced by a small number of highly specialised researchers can potentially increase the risk of bias, this niche expertise can also promote quality through increased liaison and shared practice. Future studies should subscribe to a standard format to report on the setting and sample. A complete description would include recovery status, levels of education, professional grouping, salary, tenure, professional certification/accreditation, nature of employment contract, and years of specialised experience. Response rate, missing data and attrition should also be reported uniformly. This would facilitate the equitable comparison and synthesis of data.

Conclusion

This systematic review shows that the current evidence base for factors associated with staff turnover is developing but is not yet robust. Rates of counsellors, nurses and clinical supervisors that turnover within a year show that turnover is a significant problem that needs to be addressed. The studies reviewed were generally of reasonable quality, however limitations were evident in the operationalisation and measurement of variables. All studies reviewed were based in the US indicated that research should be conducted in different geographical and organisational contexts. The findings that were synthesised, highlighted that job satisfaction is likely to be a predictor of actual turnover in substance misuse services, and should be examined further. The social and interpersonal context of staff and good quality of relational support may be an area of consideration for managers and should be an area of advocacy in organisational policies.

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Appendix I: R1 Thesis Proposal

Doctorate in Clinical Psychology

Thesis Research Proposal (for Research 1 assessment).

This form should be completed and submitted as the assessment for Research 1. It will then be reviewed by a member of the academic team and will receive a grade and detailed feedback. The feedback will include an evaluation of the viability of the project and any recommendations. If there are significant concerns about viability, the project will be flagged to the research director and the research committee will decide whether the project can proceed in its current form.

Provisional Thesis Title: A Grounded Theory of Positive Treatment Adherence for Hepatitis C Virus [HCV].

Exam number:

Allocated Thesis Project Supervisors

Clinical: Kevin Power / Kirsty Gillings

Academic 1: David Gillanders

Academic 2
(where applicable)

Others involved as part of project team (if applicable)

Proposed setting(s):
(Where research will be carried out)

Anticipated Month & Year of Submission of Thesis: 1st May
(please delete as applicable)

2015 2016

2017

(Must be in final year for full time trainees. For flexible trainees, the month & year of submission will depend on their Individual Training and Development Plan. Trainees from 2011 intake onwards must submit in May, trainees who started in 2010 or earlier are advised to submit in May to reduce potential for HPC registration difficulties)

Please Note: Whilst this is not an ethics review process, where questions have some similarities to questions contained in the NHS IRAS Research Ethics form, the corresponding IRAS question numbers are given in parentheses. This is intended to facilitate completion of NHS ethics where such approval is needed.

Version (date): 15th July 2015.

Introduction

1) **Please provide a brief critical review of relevant literature, which should clearly demonstrate the rationale and scientific justification for the research. (Relevant to IRAS A12) (Guideline 1000 to 1500)**

Scope of the Problem

Chronic hepatitis C virus (HCV) is a global public health concern, affecting over 130 million people worldwide (World Health Organisation, 2004). In 2004, the Scottish Government recognised that "hepatitis C is one of the most serious and significant public health risks of our generation" (Chisholm, 2004). An estimated 39,000 people are currently living in Scotland with HCV (Shepard, Finelli, & Alter, 2005). Regarding transmission, one prevalence study estimated that 90% of those infected acquired their virus through injecting drug use behaviour by sharing needles/syringes and other injecting paraphernalia (Roy et al., 2007). The majority of new infections occur within the intravenous drug using population (Health Protection Scotland, 2008). The health and economic toll of HCV is substantial; Vietri and colleagues (Vietri, Prajapati, & El Khoury, 2013) have sought to quantify this cost across five European countries. The research concluded that there is a significant human and financial loss associated with HCV in terms of worker absenteeism, presenteeism (impairment while at work), and general impairment in occupational functioning in those affected. Approximately one fifth of cases go on to develop cirrhosis and liver cancer (Shepard, Finelli, & Alter, 2005). UK national data shows that hospital admission rates and mortality from HCV-related liver conditions are underestimated (Palmateer, Hutchinson, McLeod, Codere, & Goldberg, 2007) and are continuing to rise (Public Health England, 2014). These findings suggest that HCV will become a significant and pervasive societal burden over the next 20 years unless more individuals successfully undergo antiviral treatment (Patruni & Nolte, 2013). Having outlined the scope of the problem globally and locally, this brief review will discuss treatment for HCV, outline treatment adherence interventions and biopsychosocial factors, identify an important knowledge gap in this area and finally propose a study to address the limitations of current knowledge and research.

Treatment and Adherence

There is significant potential for savings within the NHS and a substantial increase in economic output and productivity if more people with HCV are successfully treated. Estimates predict that quadrupling treatment rates would halt the rise in projected prevalence of HCV infection in the UK (Patruni & Nolte, 2013). Scottish Government HCV Action Plan (The Scottish Government, 2008) is a major initiative to deal with the epidemic of HCV on a national scale; it plans to increase the number of those infected receiving success full treatment, with a view to

decreasing number of people experiencing serious complications such as liver failure, for whom treatment costs are substantially higher. HCV can be effectively cured using 'combination anti-viral therapy', potentially reducing liver-related morbidity and mortality (Weiss, Bräu, Stivala, Swan, & Fishbein, 2009). While the cost of a course of antiviral therapy is, on average, £8,000, treatment is still deemed highly cost effective by both the National Institute for Health and Clinical Excellence (NICE, 2013) and Quality Improvement Scotland (SIGN, 2006). Effective treatment raises the possibility of reducing prevalence by using anti-viral therapy as prevention (Martin et al., 2011) and specifically targeting active infected drug users who are the main source of new infections (Roy et al., 2007). Despite this opportunity, under current treatment patterns, overall prevalence of Hepatitis C infection in the UK is predicted to rise by a third by 2035 (Patruni and Nolte, 2013). This indicates that while effective treatment for HCV is available, outcomes may be hindered by health behaviour.

Adherence to treatment is crucial to the success of any prescribed medication regime and is required for patients to attain a sustained virological response to HCV (Grebely et al., 2009; McHutchison et al., 2002; Mulhall & Younossi, 2005). However, a large proportion of patients (up to 50%) have difficulty in taking the recommended 80% of doses for greater than 80% of the recommended treatment duration, thereby impeding positive treatment outcomes (e.g. Grebely et al., 2011; McHutchison et al., 2002; Manos, Ho, Murphy, & Shvachko, 2013). Non-adherence is often related to undesirable side effects (e.g. Treloar, Rance, Dore, & Grebely, 2014) and complex medication regimens, including self-administered weekly injections. Treatment adherence can also be influenced negatively by psycho-social factors.

Adherence and Psycho-social Factors – Existing Literature

Sublette and colleagues (Sublette et al., 2015) argue that a lack of social support, language barriers, unstable housing, social marginalisation, discrimination and employment status play a role in non-adherence to HCV treatment (Manos, Michele, Chanda, Ho, Murphy, Rosemary, & Shvachko, Valentina, 2013; McHutchison et al., 2002). A review of the literature demonstrates further that non-persistence in HCV treatment is predicted by factors such as younger age, lower education, no or public insurance, and more severe baseline side effects (Evon et al., 2013). It is striking that the studies included in this review did not address the relationship between psychosocial factors and *positive* adherence. The lack of consideration given to the patient's perspective in published literature is equally salient. Only one recent interview study conducted by Sublette et al. (2015) has looked at facilitators of HCV treatment. Phenomenological analysis of patient interviews identified four key themes. Firstly, fear of death and alleviating stigma and shame were found to motivate patients to commence HCV treatment. Secondly, provider communication was highlighted as influential in sustaining engagement. Patients reported that

information and feedback that was personalised to their needs and lifestyles was the most effective for improving adherence to treatment. Thirdly, social, emotional and practical support improved completion of the full treatment course, as did temporarily ceasing employment.

The recent qualitative publication by Sublette et al. (2015) indicates that a psychological evidence base on HCV treatment adherence is emerging and a number of questions remain unanswered. For instance, existing research is limited in two important ways:

a). Socio-cultural Context

The aforementioned study (Sublette et al., 2015) recruited from two liver clinics in metropolitan-based hospitals in Sydney, Australia. Healthcare in Australia is provided by both private and government institutions, while in Scotland the public system dominates healthcare provision. Research suggests that patients who have the capacity to pay for private sector facilities report preferring the care they receive because of shorter waiting periods, longer or more flexible opening hours, and better availability of staff (International Finance Corporation, 2011). This aspect may have influenced the nature of the cohort recruited to this study and their subsequent HCV treatment experience. The demographic profile of the local population is also a source of contrast. According to the Scottish Index of Multiple Deprivation 2012 statistics, the level of both income, and unemployment deprivation in Dundee city is greater than in Scotland as a whole. In contrast, Sydney has been ranked tenth in the world in terms of quality of living (Mercer Co., 2009), with workers receiving the seventh highest wage levels of any city in the world (Aisslinger & Kutz, 2012). There are clear limitations in extrapolating findings from an Australia to a UK population.

b). Theoretical Approach

There are additional drawbacks regarding the philosophical position adopted by Sublette et al. (2015). These authors used framework analysis (Ritchie, Spencer, & O'Connor, 2003) within a phenomenological research design to analyse interview data. While this methodology is a useful step in allowing us to understand the subjective lived experience of HCV treatment, it does not conceptualise treatment as a social process related to specific conditions, contexts, and contingencies. Grounded theory however, explicitly examines the relationships among these elements (Strauss & Corbin, 1990). This method has potentially greater utility in the field of HCV treatment adherence research as it can be used to generate an explanatory model upon which to base interventions or future quantitative study of psychological variables.

Current Study

The current study will address the shortcomings of existing knowledge by focussing on *positive* adherence, using a grounded theory methodology, and applying this within a novel socio-economic and treatment context. This aim will be achieved by focussing on participants receiving HCV treatment in Scotland. The ERADICATE Hepatitis C trial, based in Tayside, targets younger infected drug users for HCV treatment using combination therapy. The population for the study are members of the community who attend needle exchange centres, but are otherwise not engaged with substance misuse services. The ERADICATE trial offers intensive support and regular follow up by community based nurses, and uses contingency management to support adherence. This is a unique treatment study; which does not require participants to cease injecting behaviour in order to receive treatment. Historically, before the implementation of the Hepatitis C Action Plan for Scotland II (The Scottish Government, 2008) current intravenous drug use and/or having a chaotic lifestyle would have been considered a contraindication for antiviral therapy (see Health Protection Scotland, 2008). In contrast, the ERADICATE trial does not require participants to cease injecting behaviour in order to receive treatment. The trial has been recruiting since 2013 and over 90% of participants have adhered to the treatment. This is noteworthy, given that discontinuation rates in similar clinical trial studies range from 4-27% (Mullhall & Younossi, 2005). From both a clinical and research perspective, the experiences of active and former drug users are important in generating hypotheses about the psychological processes underlying HCV treatment adherence. This is the impetus behind the current study.

Research Questions / Objectives:

(Keep these focused and concise, with a maximum of five research questions).

2) What is the principal research question / objective? (IRAS A10)

To gain a qualitative understanding of positive treatment adherence for HCV based on the self-report experience of participants who have successfully engaged in the ERADICATE trial.

To produce a grounded theory of positive treatment adherence for HCV.

3) What are the secondary research questions / objectives if applicable?

(IRAS A11)

To explore if, and how, aspects such as perceptions of the service provider and/or bio-psycho-social factors inform positive treatment adherence for HCV, should these themes emerge from the data.

Methodology

4) Please give a full summary of your design and methodology. It should be clear exactly what will happen at each stage of the project. (Relevant to IRAS A13)

Research design:

A semi-structured interview schedule will be generated and information pertaining to HCV treatment adherence will be gathered through open-ended questions (Reid, Flowers & Larkin, 2005). An interview schedule will be developed in consultation with trial nurses, clinical and academic supervisors, as well as qualitative experts at the University of Edinburgh to gain an understanding of HCV treatment adherence from the service provider perspective. This strategy is expected to enrich the interview preparation process without compromising the neutral, exploratory approach to the data. Grounded theory inquires how social structures and processes influence how phenomena occur through a given set of social interactions (Starks & Trinidad, 2007). Considering the perspective of trial staff is expected to enhance the grounded theory by recognising the dynamic relationship between patient and service provider, and the treatment context *potentially* created by this interplay.

Participants:

The population under investigation is a hard to reach, chaotic group of actively injecting intra-venous drug users, who have little contact with services. They have little or no intention of changing their drug use and engage in few harm reduction measures. This group is typically believed to be too difficult to target for treatment. It is widely presumed that the required adherence is not achievable for drug users with this stereotypical profile. However, a high proportion of this group (91.9%) have successfully engaged in the ERADICATE Trial, after being identified and selected through an urban needle exchange centre. Those participants who have engaged in the trial and adhered to the HCV treatment regime will be the subject of this research.

Effort will be made to include a sample of vulnerable participants, including women, current/former intravenous drug users, individuals who are homeless, and/or unemployed with a view to enhancing the conceptual generalizability of the grounded theory generated.

Establishing the Research Collaboration:

The two trial nurses were contacted initially and a meeting took place (April 2015) to gather more information about the HCV treatment provided by ERADICATE and the nature and number of participants who are currently engaged in the trial.

A preliminary research planning meeting has taken place (May 2015) between the Trainee Clinical Psychologist / Chief Investigator (CI) for this study, both clinical supervisors, the ERADICATE Trial Manager, the two trial nurses and the trial Chief Investigator / Grant Holder. A doctoral level qualitative was proposed and discussed. The remit of the CI as a Trainee Clinical Psychologist was clarified. Feasibility issues around data collection and ethics requirements with the timeframe available were considered. A follow-up phone call was conducted with the Trial Manager to relay the purpose and duration of thesis project. Further research group meetings with all relevant parties will take place (next scheduled for July 2015).

Procedure:

Trial nurses will be contacted further to identify a suitable pool of participants who fit the inclusion criteria, and to facilitate access to participants for interview. Demographic information about participants collected as part of the trial including participants: age, gender, employment status and current injecting behaviour (if actively using intravenous drugs, or not).

Potential participants will firstly be supplied with an information sheet by their trial nurse to make them fully aware of the interview purpose and procedure. They will also be supplied with a separate consent form and invited to return this to their trial nurse at their next clinic appointment the following week, if they are willing to participate. Once the consent form has been returned to the CI, willing participants will be contacted by phone to arrange a suitable time to conduct the interview, or, if appropriate will be asked by their trial nurse to attend their next clinic appointment one hour early, or to stay after their appointment to facilitate an interview.

The initial procedure preceding data collection is the generation of an interview schedule which captures a flexible list of topics to be covered during interview (see Table I Topic Guide). This will be informed by current literature and further developed in consultation with trial nurses, and academic staff within the University. Non-leading, open-ended questions will be compiled and short-listed with the aid of peer review. Questions will have a broad focus that is consistent with the research aim. The schedule will guide a directed conversation with the overall aim of capturing the participant's treatment experience as it relates to positive adherence. Interviews will last between 40 and 60 minutes and will be conducted privately at the trial clinic site, which is a long-standing hub of multi-service provision specifically for this population. All interviews will be audio recorded and transcribed verbatim by the researcher. For the purpose of credibility checking, a small number interviewees will be asked to feedback on the preliminary results of the grounded theory; this is expected to be highly feasible, as those who are recruited will likely continue to regularly attend clinic on a drop-in basis for the trial.

Table I: Topic Guide

Quality of care
Confidence in the experience, knowledge and skill staff regarding treatment and drug use
Provision of advice/general help; patient's need for information/education
Knowing how well the treatment is working to reduce viral load
Getting prescriptions from trial staff
Availability of treatment for active drug users
Reputation of clinic and impact of this
Psycho-social factors
Going through treatment with my partner / friend / family member.
Perception/meaning of stigma of HCV
Views of my peers / family members regarding HCV
Views of long-term benefits of treatment generally
Influence of friends/family members regarding treatment completion
Fears regarding HCV (death, contamination, infecting people who are important to me (e.g., partner, friends, children)
Confidence in the treatment and potential for cure
Knowing other people who have completed treatment successfully
Motivation to engage in treatment beyond minimal course for effectiveness
Behavioural facilitators
Rewards for treatment (e.g., shopping vouchers, protein drinks, vouchers for inviting a friend).
Access to numerous services onsite at clinic (e.g. sexual health, food parcels).
Impact of wait to treatment
Availability of appointments
Frequent contact with clinic (i.e. weekly basis).
Having appointments on the same day each week
Convenience of location (e.g., access to public transport, car parking etc)
Being able to contact my nurse outside of clinic appointments (e.g., having their mobile phone number)
Role of offer of food and drink if waiting to be seen
Time-limited nature of treatment
Treatment approach
Information on treatment; enhancing patient understanding
Choice / treatment options
Atmosphere in clinic; contrast with other healthcare environments/experiences
Contact from service (active/passive)
Communicating risks of treatment
Therapeutic alliance
Nature of relationship/partnership with trial staff
Communication from/with staff
Availability of staff

5) Please list the principal inclusion and exclusion criteria (IRAS A17-1 and A17-2)

Inclusion criteria:

- Male and females, aged 18 - 70 with chronic HCV positive infection.
- Demonstrated positive adherence to HCV treatment in the ERADICATE trial by attending weekly clinic appointments over the minimum period recommended for medication effectiveness (12 - 16 weeks depending on the genotype of the virus).
- Current or historical illicit drug use, established through drug screening (oral swab / screening) by trial nurses.
- Ability to sign and date informed consent, agreeing to study participation.
- Ability to verbally engage in a semi-structured interview conducted in English, for at least 45 minutes.

Exclusion criteria:

- Evident medical contraindications as stipulated by the ERADICATE trial (previous treatment with trial specific medication, or hypersensitivity to these products, evidence of liver failure/carcinoma, cardiac failure).
- Failure to demonstrate positive adherence to HCV treatment in the ERADICATE trial, as these participants represent a minority of participants (N=7, 8.1%) who were not able to continue in the trial due to death, or satisfactory treatment outcome *before* the minimum period recommended for medication effectiveness.
- Inability to verbally engage in a semi-structured interview conducted in English.

6) How will data be collected?

If quantitative, list proposed measures and justify the use of these measures. If qualitative, explain how data will be collected giving reasonable detail. (Don't just say 'by interviews')

Consultation will take place between the Trainee Clinical Psychologist/Clinical Investigator (CI) and the two ERADICATE trial nurses to determine which participants would be available and willing to engage with the interview study. Nurses will be able to inform the CI on demographics (age, gender) and other salient participant characteristics such as employment status, accommodation status and injecting behavior. Recruitment will take place at the city-centre needle exchange clinic where participants have weekly appointments with a trial nurse. Three clinics per week are conducted on a drop-in basis (11am – 4pm). Depending on demand, participants are usually required to wait to be seen; this period of time represents an opportunity

to recruit participants and/or collect data. Each interview will be audio taped and then transcribed verbatim for analysis. After each interview, novel content will be used to further inform the interview schedule for subsequent participants.

Sample Size

7) What sample size is needed for the research and how did you determine this? For quantitative projects, outline the relevant Power calculations and the rationale for assuming given effect sizes. For qualitative projects, outline your reasoning for assuming that this sample size will be sufficient to address the study's aims. (IRAS A59 and A60)

Grounded theory involves recruiting participants with differing experiences of the phenomenon so that the complete, multiple range of constructs that constitute the theory are fully represented by the data (Starks & Brown-Trinidad, 2007). There will aim to be a balance of heterogeneity regarding the characteristics the persons invited to interview, so that the resultant grounded theory is supported sufficiently, but does not suffer a lack of transferability to other contexts. Typical grounded theory studies report sample sizes of a minimum of 10 (Starks & Brown-Trinidad, 2007). Therefore, to address the research question adequately this study will aim to recruit at least 15 participants using a non-probabilistic, purposive sampling strategy over a 6 month period. This sample size is comparable to a similar interview study which recruited 20 participants with HCV from two urban liver clinics, over a 4 month period (see Sublette et al., 2015).

8) Outline reasons for your confidence in being able to achieve a sample of at least this size. (e.g. by giving details of size of known available sample(s), percentage of this type of sample that typically participate in such studies, opinions of relevant individuals working in that area)

Outcomes from the ERADICATE trial to date show a high rate of successful recruitment (N=86 in the first 18 months) and a relatively low drop-out / lost to follow-up rate (combined N=7; 8.1%), with 79 enrolled in the study currently. This study seeks to recruit less than a fifth of this pool of participants for interview. Recruitment to the trial will continue to be ongoing when data collection for this study begins in autumn 2015.

Trial nurses have contact with participants who discontinue treatment with a positive viral response after the minimum course of medication (3 month, 6 month, annual follow-up for 3 years). To date however, the majority of participants have remained engaged and are still

actively attending weekly clinic appointments beyond the minimum period for treatment effectiveness. Access to, and availability of the sample for the current study is deemed to be feasible within the timeframe available.

Analysis

9) Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives. (IRAS A62)

Each interview will be anonymously transcribed and labelled with the date and time of the interview. The transcript will be formatted with a margin, allowing space for additional analysis. Raw data will be repeatedly reviewed in order to establish a relationship between the text and the research question. Grounded theory methodology will be used to generate a dense conceptual explanation of positive treatment adherence for HCV. The goal is to account for most of the variability in ideas and behaviours in a purposive sample of active drug users.

The system of data analysis proposed to code the textual data is the constant comparative method for constructing a grounded theory (Glaser, 1978; Glaser & Strauss, 1967; Hutchinson & Wilson, 2001; Strauss & Corbin, 1990). As established by a review of the literature, positive treatment adherence for HCV is, as yet, an ambiguous phenomenon. Grounded theory was determined to be the optimal method as it seeks to uncover and understand what lies behind any trend about which little is yet known (Starks & Trinidad, 2007). In comparison to other methods, for example, Interpretive Phenomenological Analysis or Discourse Analysis, Grounded Theory looks for generalisability by drawing out patterns by making comparisons across a diverse sample of data. It is proposed to be particularly useful when trying to conceptualise complex change processes based on people's self-report (Wilson, Hutchinson & Holzemer, 2002; Morse & Johnson, 1991).

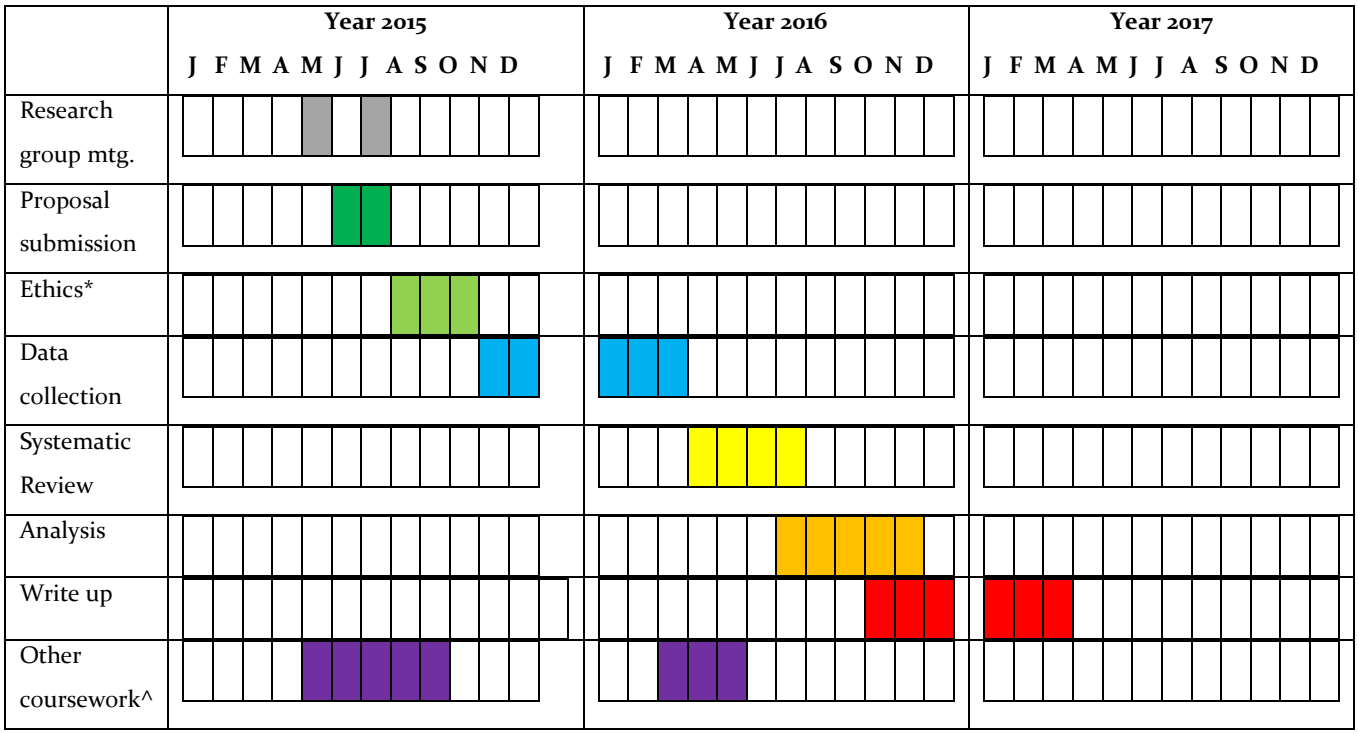
This method is sometimes considered inductive because it generates theory using a series of analytic steps that go on concurrently with data collection. The steps that will guide this study: (a) Open coding; almost each line will be taken individually and a term applied to both summarise and account for the participants' language. Codes translate the possible meaning behind the phrases and wording of the text. Coding places each unit of data in a wider context so it can be used to compare with other codes without imposing any preconceived theoretic constructions.

(b) Categorisation; open codes will be abstracted, condensed and clustered into more abstract concepts and given titles representing the similar ideas contained in each. The justification and reasoning surrounding the choice of categories will be recorded using theoretical memos.
(c) Theoretical comparison; open codes and categories will be evaluated together to generate an integrative, explanatory framework of the phenomenon under investigation.
While numerous guidelines describe how to increase the quality of qualitative research (Mays & Pope, 2000), a review of existing recommendations proposes an inclusive set of evaluative principles denoting *good* qualitative research (Cohen & Crabtree, 2008). These include ethics, pragmatism, theory, clarity, coherence and robust methodologies in qualitative research (Cohen & Crabtree, 2008). From a pragmatic perspective, Mays and Pope (2000) have identified six techniques to operationalize these criteria practically. These are outlined and applied to the current study:

1. Fair dealing: Purposive sampling will be used, however multiple perspectives will be captured as the study will seek to recruit a sample with a balance of diversity. Objectively valid generalisability will not be inferred on the basis of any one account.
2. Triangulation: Multiple interviews will be conducted. Data will be compared both within and across interviews to ensure comprehensiveness. The resultant grounded theory will be reviewed by members of the ERADICATE team to further aid triangulation.
3. Reflexivity: The researcher's prior assumptions and biases will be acknowledged and included in the analytic process and write-up. The rationale and implications of choices made by the CI will be documented in a reflective journal, which will be referred to in the final write-up. A selection of transcripts will be second coded to support the credibility of the data.
4. Member checking: The resultant grounded theory will be returned to a sample of participants in the trial to maximise congruence between the individuals' intending meaning and the researcher's interpretations and conclusions.
5. Attention to negative cases: The analysis will seek to generate explanations which accommodate the majority of cases, while examining alternative possibilities for cases, which do not appear to fit with the existing data.
6. Clarity: All interviews will be accompanied by observational notes so no data will be lost due to flawed recall or inaudibility of the tapes. Peer review will be used to enhance the clarity of the results. Extracts will be taken from the data to illustrate and substantiate the inferences made in the write-up. These strategies should provide a clear account of how codes, and categories were formed.

Project Management: Timetable

10) Outline a timetable for completion of key stages of the project. (E.g. ethics submission, start and end of data collection, data analysis, completion of systematic review).



* Ethics: Preparation, submission, and approval of ethics amendment to Patient Information Leaflet and Consent Form.

^ Other coursework: Including a R2 Small Scale Research Project (2015) and CP2 Case Conceptualization (2016).

Management of Risks to Project

11) Please summarise the main potential risks to your study, the perceived likelihood of occurrence of these risks and any steps you will or have taken to reduce these risks. Outline how you will respond to identified risks if they should occur.

Recruitment: Given the chaotic nature of the population being studied, there are risks to accessing participants for the purpose of interview. Participants may be lost to follow-up due to death, or disengagement. However, the feasibility of obtaining the required sample size has been carefully considered in the context of a high number of currently enrolled participants, who

have completed the minimum course of treatment. To date there are 79 participants enrolled in the trial and recruitment is ongoing for at least the next two years.

Supervisor absence: The current study will be supervised by both an academic and clinical supervisor. In their absence a second clinical practitioner involved in the research group will be available as a form of contingency. The CI has also developed links with other Clinical Psychology Trainees engaged in qualitative research to share expertise regarding this methodology.

Potential distress to participants: During the interview process participants will be asked about their HCV status and treatment and it is possible that asking participants to focus on this acutely personal issue may cause some distress. The CI will use a person-centred responsive interviewing style to build trust and minimise the potential for upset within the conversation (Rubin & Rubin, 2012). The participant information sheet will direct the participant to raise any concerns or questions regarding the study with their trial nurse with whom they have regular contact. Participants will also be reminded on the information sheet that participation is voluntary, that they are free to withdraw at any point i.e. retract the consent for their data to be used and that their continuity of care will not be affected by their participation or non-participation in the study.

Multiple stakeholders: Linking with a clinical drug trial represents both a risk and significant opportunity for the current thesis project. The CI should liaise closely with the Trial Manager and nurses. Increased collaboration means decreased autonomy, as the purpose and outcome of the research needs to meet a mutually beneficial aim for all stakeholders. Clarity of communication between all involved parties and contingency planning will be of paramount important in carry out the research. To date one large research group meeting has taken place and proved a useful opportunity to build working relationships. While the CI is required advocate for the needs of a Trainee Clinical Psychologist, the experience of working with a research group is deemed to be a valuable and relevant learning opportunity which is supported by the CI's Clinical Supervisors, Line Manager and Head of Service.

As the trial is funded by companies in the pharmaceutical industry, conflict of interest may arise regarding the use of participant data. However, as stipulated in the ERADICATE trial protocol, ownership of the data resides with the study team and their respective collaborators (i.e. the CI for this study) and funders are not stated to have nay rights of access to the data. Data analysis and reporting is understood to be permissible for written or oral dissemination in the form of a doctoral thesis, journal publication or presentation at scientific meetings.

Knowledge Exchange

12) How do you intend to report and disseminate the results of the study? (IRAS A51)

This study will be submitted in part fulfillment of Doctorate in Clinical Psychology, as such the thesis will be available through the University of Edinburgh library. Each participant will be given a written summary of the study findings. The study will be presented to the ERADICATE trial team, particularly the role of service provision on positive treatment adherence. The study will be presented at the NHS Tayside Psychological Therapies Departmental meeting. The related systematic review and empirical study will also be submitted to an appropriately identified peer-reviewed journal for consideration e.g. Qualitative Health Research, Psychology and Health. The study will be seek to be presented at national and international scientific meetings and conferences e.g. International Conference on Viral Hepatitis and Liver Diseases, The Viral Hepatitis Congress, European Conference on Hepatitis C and Drug Use.

13) What are the anticipated benefits or implications for services of the project? (E.g. If this is an NHS based project, in what way(s) is the project intended to benefit the NHS?)

While HCV mainly spreads through intravenous drug use, particularly sharing needles, active drug users are not currently offered HCV eradication treatment. This group typically leads a very chaotic lifestyle which makes it difficult for them to engage with services and to comply with the strict treatment routines and required medical follow up. The proposed study links to a pioneering trial which does not withhold treatment on this basis. This research seizes a valuable opportunity to capture the rich detailed treatment experience of active drug users in Scotland. This is a marginalised and stigmatised population, whose unique socio-cultural experience is not represented in existing literature.

A technical report from Oxford University and Rand Europe Co. (Patruni & Nolte, 2013) demonstrates that there are significant public health benefits to lowering the pool of individuals with HCV infection, and that this is possible even if people are still injecting drugs. There is also the potential for significant savings for the NHS and significant increase in economic output and productivity if more people with Hepatitis C are successfully treated. They proposed that quadrupling treatment rates would halt the rise in projected prevalence of HCV infection in the UK (Patruni & Nolte, 2013). Treatment adherence is a crucial variable in treatment success. The process by which adherence is achieved should be therefore be understood and used to enhance interventions. Producing a grounded theory of positive HCV treatment adherence in drug users

who currently inject, or not, can be used to inform future HCV treatment trials under the remit of the ERADICATE team, and beyond.

Evon, Golin, Fried and Keefe (2013) argue for the particular expertise of Clinical Psychologists in understanding, managing and evaluating the complex interplay between bio-psycho-social factors, antiviral treatment and HCV health outcomes. The current study explores this assertion, and the data from this study may support a more robust role for CPs within clinical health specialties such as hepatology. While CPs hold relevant clinical knowledge and skills, they can also contribute to health economic activity (research, policy development), where HCV is particularly salient concern.

14) Are there any potential costs to this project?

Outline any potential financial costs to the project, including the justification for the costs (why are these necessary for the research project?) and how funding will be obtained for these costs (how will cost be met?). Please separate these into potential costs for the University and potential costs for your NHS Health board and note that you should ask your NHS Health board to meet stationery, printing, postage and travel costs.

Participants in the trial will be offered small reward, of a £5 supermarket voucher to incentivise them to take part in the study. Given the effectiveness of contingency management with the cohort so far, such remuneration is expected to significantly enhance recruitment to the study. Funding for this would be secured from the health board Psychology Department budget; this request has already been informally approved by the Head of Service.

15) Any other relevant information.

N/a.

16) Key References

Aisslinger, M., & Kutz., R. (2012). UBS Prices and earnings 2012, (September), 46. Retrieved fromhttp://www.ubs.com/global/en/about_ubs/media/global/releases/news_display_media_global.html.html/en/2012/09/14/20120914a.html

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17) Confirmation of Supervisors' Approval

I confirm that both my academic and clinical supervisors have seen and approved this research proposal and have both completed the supervisors' appraisal forms below.

(Insert 'yes' below if true)

YES

Appendix II:

Methodological Review

Main Academic Thesis Supervisor's Appraisal of Project Risk

Supervisor's Name: David Gillanders

Do you consider that the project should proceed in broadly its current form?
(Delete as appropriate)

Yes

Please outline the reasons for your response. In particular, highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks:

My view is that this proposal outlines a useful question around understanding adherence in a marginalized group and a method that is capable of addressing that question. The student has already started to establish the necessary relationships within the research context that will be vital for the success of this study. The quality of thinking in terms of the methodological choices and procedures also seems good to me, given the first year stage if training that this student is at. The project appears well supported in the clinical context. My view is that it is feasible, that this student will be able to deliver it and that it will lead to new knowledge that would be a suitable subject for the doctoral thesis.

Date: 8th July 2015

Appendix 2.

Methodological Review

Clinical Thesis Supervisor's Appraisal of Project Risk

Supervisor's Name: Kevin Power

Position: Head of Service

Do you consider that the project should proceed in broadly its current form?
(Delete as appropriate)

Yes ✓ Yes, subject to revisions outlined below No

Please outline the reasons for your response. In particular highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks:

The Chief Investigator for the Endicott programme initiated the request for research in this area. There is therefore strong local support for the project that is theoretically sound and clinically relevant. The model of service provision also facilitates access to this difficult to reach group of participants

Date:

Appendix III: Sample Line-by-Line Coding

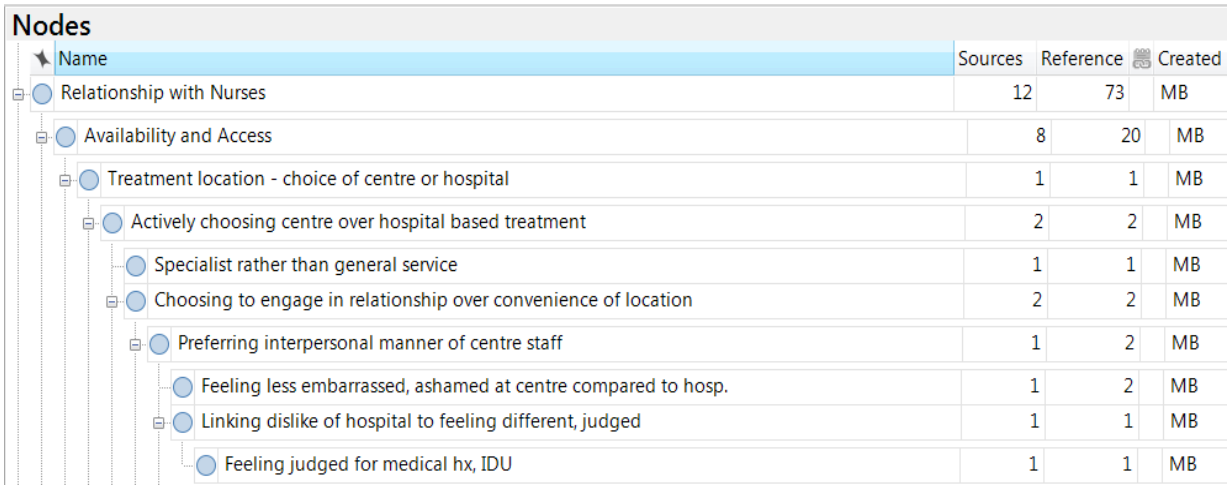
Interview #12: Gemma – Segment 05:38 – 09:54

I: I'm wondering what was good about that aspect [talking to the nurses], what was helpful?	
G: Ehm… I spose because I'm getting' it out an' not keepin' it all in an' they're listin' to you an'… yeh they were easy to speak to	Talking and sharing was helpful Feeling listened to
I: They were easy to speak to?	
G: Yeh	Nurses were easy to talk to
I: I guess was there anything else you felt about them or about this place?	
G: Yeh they were really friendly they make ya they're really friendly an' tha' they don' make you don't feel awkward abou' gettin' the treatment or stuff like tha' because they they're dead nice abou' it yeh… they make you feel really .. they make you feel good they're always chatty an' nice wi' ya they' were wi' me so	Experienced friendliness Feeling comfortable with nurses Linking kindness to ease with treatment Consistent warmth increased positive emotion
I: You felt listened to and able to share with the nurse.	
G: Yeh you did yeh you really did they were jus' good to speak to I still speak to [name of nurse] an' tha' if I see them no they were they were really good [whispers] stealin' a biscuit [takes a biscuit]	Experienced benefit from talking Ongoing relationship post-treatment Commending nurses
I: Of course, go ahead. And you mentioned that you'd been coming to the [name of Centre] for a while before actually starting the trial?	
G: Years	Attended centre for years
I: A few years, wow, so did that make a difference?	
G: …probably ehm cos' I was familiar wi' comin' in an' out	Previous familiarity with setting was influential
I: It was somewhere you were familiar with?	
G: Yeh an' I know it's abou' it's where you used to get yer needles an' stuff so yer not sorta judged here cos you know wha' yer here for if ya know wha' I mean tha' is important	Used needle exchange facility Stating importance of not feeling judged for IDU
I: Something that's come up with other people I've spoken to is that people felt different coming to this centre rather	

than going to hospital. Would you have any thoughts about that?	
G: I would rather come here than go to the hospital just the the sp.. they're more down to earth they're more nice they're a lot nicer wi' ya like the hospital's dead formal an' then you you feel .. at ease here you didn' feel embarrassed or tha' here like if I was at the hospital I would feel embarrassed an' ashamed an' stuff eh but here I didn' cos I know that's the.. work wi' I know the hospital work wi' everybody but this is all they do an' they're just really nice you didn' feel any awkwardness or tha' somehow so	Preferring centre to hosp. Contrasting interpersonal manner of staff Hosp. is more formal Feeling embarrassed, ashamed at hosp. Feeling more at ease at centre Specialist IDU services provide more sensitive care than general Linking comfort to staff experience, approach
I: Have you had different experiences in hospital?	
G: When I went to hospital when I had DVT yeh you feel horrible it's not nice it's not good	Previous negative experience at hosp.
I: What was it about it?	
G: Jus' the people the way they… I mean when I got ma' x-ray you see the staff all lookin' at one another like 'ken jus' wi' the eyes an' stuff an' you know it's abou' what's on .. it's jus' not you jus' dinnae feel good eh well I didn' if I was here gettin' the x-ray done they would be speakin' to me and sayin' it's jus' it's jus' different you jus' don't feel like tha' I jus' didn' like the hospital at all	Perceived stigmatising body language from hosp. staff Feeling judged for medical hx, IDU Contrasting staff approach at centre Being talked to, procedures explained Linking dislike of hospital to feeling different, judged
I: Do you think if the ERADICATE treatment was offered at the hospital you would've.. [cut-off]	
G: [shakes head] No no only done it cos it was here	Engagement strongly linked to location
I: Only because it was here, so that was really important?	
G: Ah-huh as soon as you get to it I knew the place cos I used to come anyway if I had to start tha' at the hospital I don't think I woulda went all the way through probably woulda went the first once or something I wouldn' went back so yeh it is important where ya get it	Previous familiarity with centre as key Predicting disengagement f/m hosp. Would not have engaged fully Stating importance of treatment setting

Appendix IV: Sample Axial Coding

Screen snip of axial coding leading to higher order clusters (NVivo 11.0 “nodes”) from line-by-line codes:



Nodes

Name	Sources	Reference	Created
Relationship with Nurses	12	73	MB
Availability and Access	8	20	MB
Treatment location - choice of centre or hospital	1	1	MB
Actively choosing centre over hospital based treatment	2	2	MB
Specialist rather than general service	1	1	MB
Choosing to engage in relationship over convenience of location	2	2	MB
Preferring interpersonal manner of centre staff	1	2	MB
Feeling less embarrassed, ashamed at centre compared to hosp.	1	2	MB
Linking dislike of hospital to feeling different, judged	1	1	MB
Feeling judged for medical hx, IDU	1	1	MB

Appendix V. Sample Journal Entries

[Excerpt] Entry #29. 06/06/15 - Socio-cultural context and researcher responsibility.

The status of my participants in society is one of social and economic disadvantage and deprivation. They are the "down-trodden" - people that are unseen, unheard and unwanted. I just came across an article talking about a sculpture exhibition in London. It was a plaster-cast of a human figure wrapped in a bin bag hunched over, and placed on the street. The title was "Left Out"; what a moving and visceral depiction of homelessness. These images[8] (see below) are such powerful metaphor for degradation, shame, worthlessness. What a visceral way of depicting our perception of people on the street; how it's so much easier to see a bag of rubbish than a human being, a person, people like my participants. And while this is art, my eyes fill up recalling "Jack", the man that who in front of me wearing a black plastic bag under his clothes, knowing that when he left the interview room he would sleep on the street.

And what is the role of research within Clinical Psychology in society, in this context around PWID and homeless populations? The argument is that by only giving these people a voice through the medium of research, and doing so in a discreet and sanitised way for the purposes of journal submission, that we are complicit in maintaining an "us" and "them". As researchers we are in a position of power; as a university educated, middle-class, professional I am incredibly privileged be the one sitting on my sid[1]e of the table, asking the questions. In a way, I "allowed" people to speak about their experience. Does research with vulnerable group implicitly reinforce their "otherness" and "less than-ness"? Were the moments of misattunement, or not feeling truly

[8] http://maxwellrushton.com/projects/left-out/

able to identify with my participant's experiences and their internal world, a kind of transference, reflecting how they feel? Is this related to a theme of connection-disconnection?

[Excerpt] Entry #33. 29/07/15 – Post S/v w. DG. (#12) - Macro-level interpretations in qualitative analysis.

Interesting discussion with DG around the tension between clinical psychology as an empirical, positivist science and the social constructivist approach of grounded theory. Important to remember that the dichotomy is false and inaccurate. The purpose of qualitative research is not to establish an objective truth, but it is about making intentional choices about what I'm doing and why I'm doing it that way. Is it useful? How? Qualitative research be hugely helpful in developing quantitative hypotheses and in this way they are two sides of the same coin.

While staying faithful to the empirical process is undoubtedly important, the finished article is read and heard, how findings translate to practice is equally, if not more important than using lots of jargon in the description. We need to be conscious of capturing and translating the richness of the data in the reporting and analysis – staying grounded in the data. As long as we write consciously for a readership situated in mainstream psychological science, we can navigate the tension that may arise between preserving authenticity and writing with an academic tone.

Appendix VI: Participant Consent Form

Study Ref.: 2012GA01 Participant Id : ……

Title of Study: Exploring Treatment Experience within the ERADICATE Trial

Name of Researcher: Chief Investigator: Prof. John Dillon; Study Investigator: Maeve Butler.

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care, treatment within the ERADICATE trial, or legal rights being affected. ☐

3. I understand that relevant sections of my data collected during the study may be looked at by the research team or the regulatory authorities, NHS Tayside, or the University of Dundee (or their appointed third party), where it is relevant to my taking part in this study. I give permission for these Individuals to have access to my data. ☐

4. I understand that my interview will be audio recorded and transcribed by members of NHS Tayside. I give permission for these Individuals to have access to my data. ☐

5. I understand that the data collected about me in this study will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

   OPTIONAL

6. I understand that I may be contacted again to give feedback on the conclusions drawn by the researcher in relation to this study. ☐

7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking consent	*Date*	*Signature*

Quality Criteria for Systematic Review

Question: What are the factors associated with staff turnover in substance misuse services?

Title and Abstract

1. Statement of purpose:

2 points	Title clearly indicates the study design and variables being examined. Abstract provides a clear, succinct summary of method and salient outcomes.
1 points	Title does not clearly indicate the study design and variables being examined. Abstract provides a partial/unclear summary of method and salient outcomes.
0 points / NA	Not addressed / reported / applicable.

Introduction

2. Rationale & objectives:

3 points	Primary research question is clearly described and substantiated by a clear, theoretically informed *a priori* hypotheses.
2 points	Primary research question is adequately described. Hypotheses are proposed with partial clarity. The theoretical supposition informing the hypothesis is not theoretically robust, is unclear in the context of the study, or only describes minimal background literature.
1 point	Primary research question is poorly or insufficiently described. Hypotheses are not stated, or not informed by theory, or supporting literature, or evidence has been misunderstood/misappropriated leading to unfounded inferences.
0 points / NA	Not addressed / reported / applicable.

Method

3. Design:

3 points	Study design is clearly described, and appropriately addresses the association between variables of interest (e.g. correlational, cross-sectional, longitudinal).
2 points	Study design is adequately described, but only partially addresses the association between variables of interest, but this can be inferred (e.g. group comparison).
1 point	Study design is poorly or insufficiently described, without reference to the association between variables of interest (e.g. case study).
0 points / NA	Not addressed / reported / applicable.

4. Setting and recruitment:

3 points	Setting (e.g. organisation structure – inpatient, outpatient, and service provision – intensive, methadone maintenance), location and recruitment method (e.g. inclusion criteria, periods of recruitment, follow-up, and data collection) are clearly described and appropriate.
2 points	Inclusion criteria, setting and recruitment method are adequately described.
1 point	Inclusion criteria, setting and recruitment method are poorly or insufficiently described, with significant omissions.
0 points / NA	Not addressed / reported / applicable.

5. Data source:

3 points	Data source is clearly described (e.g. who provided what proportion of turnover information and where the information was originally logged). Data is cross-referenced with at least one other source, if appropriate (e.g. secondary analysis).
2 points	Data source is adequately described but incomplete, and is cross-referenced, if appropriate.
1 point	Data source is poorly or insufficiently described, and is not cross-referenced, if appropriate.
0 points / NA	Not addressed / reported / applicable.

6. Variables:

3 points	All variables of interest (outcomes, predictors, modifiers) are clearly defined and operationalised appropriately. The outcome variable of interest, staff turnover is expressed as a rate, for which the formula used is described.
2 points	Variables are adequately defined operationalised. Staff turnover is operationalised as a rate / numerically, but the formula used is not described.
1 point	Variables are not defined or poorly or insufficiently operationalised. Staff turnover is not expressed numerically.
0 points / NA	Not addressed / reported / applicable.

7. Reliability and validity of measures:

3 points	Standardised/objective measures are used to assess factors associated with staff turnover and have good internal reliability and validity.
2 points	Measures used to assess factors associated with staff turnover have adequate internal reliability and validity.
1 point	Measures used to assess factors associated with staff turnover have poor internal reliability and validity, or have been developed for the purpose of the study.
0 points / NA	Not addressed / reported / applicable.

8. Statistical methods:

2 points	Method of statistical analysis, and rational is clearly described and appropriate.
1 points	Method of statistical analysis, and/or rational is not clearly described, or is inappropriate.
0 points / NA	Not addressed / reported / applicable.

Results

9. Descriptive data:

3 points	Sample is clearly described, including full characteristics of staff (e.g. education, professional grouping, years of experience, tenure, annual salary) and demographics (age and gender).
2 points	Sample is adequately described, with some incomplete characteristics of staff and/or demographics.
1 point	Sample is poorly or insufficiently described, with significant omissions regarding characteristics of staff and/or demographics.
0 points / NA	Not addressed / reported / applicable.

10. Power of sample size:

3 points	Power calculation is reported and sample size adequately meets the recommendation for the analysis conducted, or comments on being underpowered.
2 points	Power calculation is not reported, but sample size is estimated to adequately support the analysis conducted.
1 point	Power calculation is not reported, and sample size is not estimated to support the analysis conducted, but this is commented on.
0 points / NA	Not addressed / reported / applicable.

11. Representativeness of sample:

2 points	Number of individuals eligible for inclusion, and number who were included (i.e. who responded) are reported. Reasons for non-inclusion / non-response are clearly described.
1 point	Number of individuals eligible for inclusion is not reported, but number who were included is reported. Reasons for non-inclusion / non-response are not clearly described.
0 points / NA	Not addressed / reported / applicable.

12. Outcome data:

3 points	Outcomes from statistical analysis (relevant descriptive and inferential data) are clearly reported. The statistical significant of associations between variable is reported.
2 point	Outcomes from statistical analysis are adequately reported, though maybe unclear.
1 point	Outcomes from statistical analysis are poorly or insufficiently reported, and are unclear.
0 points / NA	Not addressed / reported / applicable.

13. Treatment of confounds:

2 points	Confounding variables clearly identified and adjusted for. Unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval) are provided.
1 point	Some potientially confounding variables are identified and controlled for in part of the analysis, but full description is not provided.
0 points / NA	Not addressed / reported / applicable.

14. Attrition:

2 points	Attrition (drop-out) rate and explanation is clearly described.
1 point	Attrition rate is stated but explanation is poor, or not described.
0 points / NA	Not addressed / reported / applicable.

15. Missing data:

2 points	Missing data, and handling in analysis is clearly reported. Robust steps made to minimise bias.
1 point	Missing data is adequately reported, but unclear handling in analysis. Some steps made to minimise bias.
0 points / NA	Not addressed / reported / applicable.

Discussion

16. Key results:

3 points	Results are clearly summarised and address the association between variables as indicated by the research question/hypotheses.
2 points	Results are adequately summarised; the association between variables is not fully addressed, but this can be inferred.
1 point	Results are poorly summarised; the association between variables is not addressed.
0 points / NA	Not addressed / reported / applicable.

17. Limitations:

2 points	Limitations (e.g. bias, imprecision) and implications for findings are clearly described.
1 points	Limitations and implications for findings are adequately described.
0 points	Limitations and implications for findings are poorly or insufficiently described.
0 points / NA	Not addressed / reported / applicable.

18. Interpretation and generalisability:

2 points	Conclusions and overall interpretation of results are appropriately cautious and consider objectives, limitations, analyses, and existing evidence. The generalisability of results is commented on.
1 point	Conclusions and overall interpretation of results are not appropriately cautious and/or do not consider objectives, limitations, analyses, and existing evidence. The generalisability of results is not commented on.
0 points / NA	Not addressed / reported / applicable.

19. Funding/Acknowledgements:

1 points	Source of funding and role of funders in study described and, if applicable, description of the original study on which on which the article is based.
0 points / NA	Not addressed / reported / applicable.

NHS SCOTLAND

Research Ethics Service

East of Scotland Research Ethics Service (EoSRES)

Tayside Medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Dr John Dillon
Ninewells Hospital
Dundee
DD1 9SY

Date: **9 December 2015**
Your Ref:
Our Ref: AG/12/ES/0071
Enquiries to: Arlene Grubb
Direct Line: 01382 383848

Dear Dr Dillon

Study title:	**Eradicate Hepatitis C Virus- a pilot of treatment as prevention in active drug users (ERADICATE HCV)**
REC reference:	**12/ES/0071**
Protocol number:	**version 1 03/08/2012**
Amendment number:	**AM04(REC reference only)**
Amendment date:	**18 November 2015**
IRAS project ID:	**112710**

The above amendment was reviewed [at the meeting of the Sub-Committee held on 03 and 08 December 2015 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper		18 November 2015
Notice of Substantial Amendment (non-CTIMP)	AM04	18 November 2015
Other [Response to request for further information]		08 December 2015

Other [CV - Maeve Butler]		20 August 2015
Participant consent form	1.0	02 November 2015
Participant information sheet (PIS)	1.0	02 November 2015
Research protocol or project proposal	1.0	02 November 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

12/ES/0071: Please quote this number on all correspondence

Yours sincerely

Arlene Gubb

For Dr Anthony Davis

Vice Chair

E-mail: eosres.tayside@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Mrs Liz Coote, NHS Tayside

East of Scotland Research Ethics Service REC 2

Attendance at Sub-Committee of the REC meeting on 03 December 2015

Committee Members:

Name	Profession	Present	Notes
Dr Anthony Davis	Consultant Anaesthetist	Yes	Expert, Vice Chair
Dr Stuart Paterson	Consultant Physician	Yes	Expert

Also in attendance:

Name	Position (or reason for attending)
Mrs Lorraine Reilly	Senior Co-ordinator

Written comments received from:

Name	Position
Dr Anthony Davis	Consultant Anaesthetist
Dr Stuart Paterson	Consultant Physician

SCHOOL *of* HEALTH IN SOCIAL SCIENCE

CLINICAL AND HEALTH PSYCHOLOGY

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891

Maeve Butler
Trainee Clinical Psychology
University of Edinburgh

30 April 2017

Dear Maeve,

Ethical Approval

Project Title:	ERADICATE Trial: Exploring Treatment Experience
Acade24 April 2017**mic Supervisor:**	David Gillanders

Thank you for registering the above research project with the Department of Clinical and Health Psychology Ethics Research Panel. I can confirm that application submitted to NHS R&D panel been reviewed and was approved as meeting university requirements.

Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

Angus MacBeth,

Ethics Tutor, Clinical Psychology

Appendix IX: Author Guidelines (relevant extracts)

Harm Reduction Journal

Preparing your manuscript: The information below details the section headings that you should include in your manuscript and what information should be within each section. Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information)

Title page: The title page should:

- present a title that includes, if appropriate, the study design e.g.:
  - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
  - or for non-clinical or non-research studies a description of what the article reports
- list the full names, institutional addresses and email addresses for all authors
  - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

Abstract: The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study was performed and statistical tests used
- **Results:** the main findings
- **Conclusions:** brief summary and potential implications
- **Trial registration:** If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration

Keywords: Three to ten keywords representing the main content of the article.

Background: The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

Methods: The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
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